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SERVICE MANUAL REVISION LOG
(Please record any changes made to this manual)

Revision Number	Release Date	Approved By	Description
A	Nov 94		Released
B	Nov 95		Updated per CO 090226
C	Aug 97		Updated per CO 970334
D	Sep 98		Updated per CO 980329
E	Mar 01		Updated per CO 010134
F	Nov 01		Updated per CO 010614
G	Nov 02		Updated per CO 020642
H	Mar 04		Updated per CO 031357

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PD7005-H

Important Information! Important Information!

This Service Manual contains important **warnings** and **safety information** to be observed by the user.

This instrument is only intended for one area of application which is described in the instructions. The most important prerequisites for application, operation and safety, are explained to ensure smooth operation. No warranty or liability claims will be covered if the instrument is applied in areas other than those described or if the necessary prerequisites and safety measures are not observed.

The instrument is only to be operated by qualified personnel capable of observing these prerequisites.

Only accessories and supplies either delivered by or approved by Osmetech Inc. are to be used with the instrument.

Due to this instrument‘s operating principle, analytical accuracy not only depends on correct operation and function, but also upon a variety of external influences beyond the manufacturers control. Therefore, the test results from this instrument must be carefully examined by an expert, before further measures are taken based on the analytical results.

Instrument adjustment and maintenance with removed covers and connected power mains are only to be performed by a qualified technician who is aware of the dangers involved.

Instrument repairs are only to be performed by the manufacturer or qualified service personnel.

Important Information! Important Information!

Operating Safety Information

- Overvoltage Category II when connected to a branch circuit.
- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules.

Caution:

- The instrument is designed as a conventional device (closed, not waterproof type).
- Do not operate the instrument in an explosive environment or in the vicinity of explosive anesthetic mixtures containing oxygen or nitrous oxide.
- This instrument is suitable for continuous operation.
- The power plug is to be plugged into a ground socket only. When using an extension cord, make sure that it is of the proper size and is properly grounded.
- Any breakage of the ground lead inside or outside the instrument or a loose ground connection can cause a hazardous condition when operating the instrument. Intentional disconnection of the grounding is not permitted.
- When replacing the fuses, make sure that they are of the same type and rating as the original fuses. Never use repaired fuses or short-circuit the fuse holders.

This device is a Class 1 Laser product according to the requirements of IEC 60825-1. The maximum energy output is as follows:

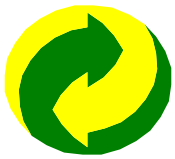
670 nm (LED): 40 Microwatts max. for 400ms
780 nm (Laser): 40 Microwatts max. for 400ms
850 nm (Laser): 40 Microwatts max. for 400ms

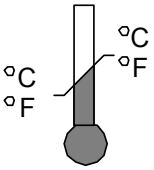
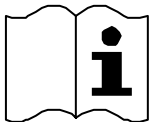
Caution - Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

Operating Safety Information

Symbol Definitions

The symbols described below are used on the packaging of Osmetech OPTI related products.

Symbol	Explanation
	Attention Symbol – Refer to the Operator's Manual or Service Manual for further instructions. This symbol is located on the inside of the instruments and product packaging.
	Expiration / Use By Symbol – Product to be used by the expiration date indicated to the right of this symbol. This symbol is located on all consumables, which are controlled via an expiration or use by date.
	Batch Code Symbol – Manufacturing lot number is located to the right of this symbol. This symbol is located on all products, which are controlled via a lot number.
	Do Not Re-use Symbol – Identifies products which are <u>not</u> to be used for more than the specified period of time as defined in the product instructions. This symbol is located on all applicable product packaging.
	Recycle Plastic Symbol - Identifies the clear plastic material (polyethylene terephthalate glycol) used in the packaging of the product. Containers identified with this symbol can be considered recyclable. This symbol is located on all applicable product packaging.
	Green Dot Symbol - Indicates compliance with the German Packaging Ordinance for the return of consumer packaging. This symbol is located on all applicable product packaging.

Symbol	Explanation
	Bio-Hazard Symbol – Products and/or components containing this symbol should be handled as bio-hazardous material after use.
	Temperature Symbol – Products and/or components which contain this symbol must be stored between the specified temperature range.
	For in vitro diagnostic use
	This product fulfils the requirements of Directive 98/79/EC on in vitro diagnostic medical devices.
REF	Catalogue number
	Please read pack insert. / Follow the instrument's instructions for use!
	Manufactured by

1 Introduction

General Information

This Service Manual includes information and data necessary for repair and maintenance of the Osmetech OPTI™ 1 and Osmetech OPTI™ CCA analyzers. The manual is intended to be used with the Operator's Manual where operating instructions and procedures are described. In order to fully utilize the described procedures in this manual, it is necessary to be familiar with the operation and handling described in the Operator's Manual.

To ensure proper operation and performance which meets the analyzer specifications, maintenance and repairs must be performed according to the instructions described in this service manual. The use of Osmetech original parts and recommended materials is required to achieve performance specifications. Spare parts and the proper order numbers are described in Chapters 7 and 8.

Product warranties may vary by country. Specific warranty terms and conditions are described in documents provided at the time of installation.

Warnings

Warnings in this manual are marked with CAUTION and describe situations or potential dangers that may be hazardous to personnel performing maintenance or service activities. Information marked with NOTE describes situations or hazards, which can cause damage or analyzer malfunction and should be avoided. The following general operating conditions should be strictly adhered to:

- Never operate the analyzer near flammable or explosive gases.
- Check the supply voltage before connecting the analyzer to local AC power.
- When operating the analyzer connected to primary AC power, always connect it to a properly grounded 3-pole power receptacle.
- Replace damaged or worn power cables or plugs.
- Before opening the rear cover, turn off the analyzer, disconnect the power cable from the primary AC source and remove the battery.

- Replace fuses with approved or original types only.
- Operate the analyzer away from sources of liquids such as sinks or wash basins.
- Avoid leakage or spilling of fluids inside the analyzer, which may damage the electrical assemblies.
- Clean the analyzer surfaces with only a mild soapy solution as necessary. Avoid strong or harsh chemical cleaning agents that may damage the analyzer housing and surfaces.
- Use proper tools and test equipment as described in this manual to complete testing and repairs.

- Analyzer surfaces may be contaminated from contact with blood. Always use precaution when coming into contact with these surfaces.

- Use approved protective gloves when handling blood specimens of contacting contaminated surfaces.

- Adhere to local regulations when disposing of Osmetech OPTI cassettes or contaminated parts.

2 General Description

Specifications

Measurement Parameters

The specifications are described for both the Osmetech OPTI™ 1 and Osmetech OPTI™ CCA analyzers. Certain parameters are specific only to Osmetech OPTI™ CCA analyzers.
The specifications listed below are valid for human whole blood, human plasma, serum, and approved QC-material.

Parameter	Range	Display Resolution (Lo / Hi)	Units	Osmetech OPTI 1	Osmetech OPTI CCA
pH	6.6 - 7.8	0.01 / 0.001	pH units	✓	✓
PCO_2	10 - 200	1 / 0.1	mmHg	✓	✓
PO_2	10 - 700	1 / 0.1	mmHg	✓	✓
Na+	100 - 180	1 / 0.1	mmol/L		✓
K+	0.8 - 10.0	0.1 / 0.01	mmol/L		✓
Ca++	0.2 - 3.0	0.01	mmol/L		✓
Cl-	50.0 - 160.0	1 / 0.1	mmol/L		✓
Glu	30 - 400	1 / 0.1	mg/dl		✓
Glu	1.7 - 22	1 / 0.1	mmol/l		✓
ctHb	5 - 25	0.1	g/dL		✓
SO_2	60 - 100	1 / 0.1	%		✓
Barometer	300 - 800	0.1	mmHg	✓	✓

Input Values		Range *	Default Value	Osmetech OPTI 1	Osmetech OPTI CCA
Patient Temperature	Temp	14 - 44 °C 58 - 111 °F	37.0 °C 98.6 °F	✓	✓
Total Hemoglobin	tHb	1 - 26 g/dL 1 - 16 mmol/L 1 - 260 g/L	15.0 g/dL 150 g/L		✓
Total Hemoglobin	ctHb	1 - 26 g/dL 1 - 16 mmol/L 1 - 260 g/L	15.0 g/dL 150 g/L	✓	✓
Hemoglobin type		adult / fetal	adult	✓	✓

Input Values	Range *	Default Value	Osmetech OPTI 1	Osmetech OPTI CCA
P_{50}	15 - 40 mmHg	26.7 mmHg	✓	✓
FIO_2	0.21 - 1.0	0.21	✓	✓
Respiratory Quotient, RQ	0.7 - 2.0	0.84	✓	✓
Patient Id	11 digits max.			✓
Patient Sex	male / female / ?	? (unknown)	✓	✓
Operator Id	11 digits max.			✓
*SI units are also available.				✓
Accession Number	Blank to 999999999999			✓
Puncture Site	LR/RR/LB/RB/LF/RF/ Cord/Scalp Where: LR = Left Radial RR = Right Radial LB = Left Brachial RB = Right Brachial LF = Left Femoral RF = Right Femoral Cord = Cord Scalp = Scalp	LR		✓
Bypass	Off Pump / On Pump	Off Pump		✓
Sample Type	Art, Ven, MixVen, Cap, Cord, CPB Where: Art = Arterial Ven = Venous MixVen = Mixed Venous Cap = Capillary Cord = Cord CPB = Cardio-Pulmonary Bypass	Art		✓
Mean corpuscular hemoglobin concentration, MCHC%	29.0 to 37.0	33.3		✓

Input Values	Range *	Default Value	Osmetech OPTI 1	Osmetech OPTI CCA
O2 Mode	Rm Air, Mask, T-P, NC, Vent, Bag, Hood or Other Where: Rm Air = Room Air Mask = Mask T-P = T- Piece NC = Nasal Cannula Vent = Ventilator Bag = Bag (manual resuscitation) Hood = Hood Other = Other	Rm Air		✓
Vent Mode	No, SIMV, PSV, PCV, CMV/AC, CPAP, PCIVR or BIPAP Where: No = None SIMV = Synchronized Intermittent Mandatory Ventilation PSV = Pressure Support Ventilation PCV = Pressure Control Ventilation CMV / AC = Controlled Mechanical Ventilation / Assist Control CPAP = Continuous Positive Airway Pressure PCIVR = Pressure Control Inverse Ratio BIPAP = Bi – Level Positive Airway Pressure	No		✓
Tidal Volume (VT)	0 to 4000	0		✓
Minute Volume (VE)	0 to 120	0		✓
Peak Inspiratory Pressure (PIP)	0 to 140	0		✓
Plateau Pressure(Pplat)	0 to 100	0		✓
Pressure Support Value (PS)	0 to 99.9	0		✓
Positive End Expiratory Pressure (PEEP)	0 to 50	0		✓
Continuous Positive Airway Pressure(CPAP)	0 to 50	0		✓

Input Values	Range *	Default Value	Osmetech OPTI 1	Osmetech OPTI CCA
Rate (f)	0 to 155	0		✓
Flow Rate (Liter Flow) (FR)	0 to 300	0		✓
Inspiratory/Expiratory Ratio (I/E Ratio)	1:9.9	0		✓
Bi-Level Pressure	0 to 99.9 / 0 to 99.9	0 / 0		✓
User Field	blank to 999999999	Off		✓
User Field 2	blank to 999999999	Off		✓
User Field 3	blank to 999999999	Off		✓

Calculated Values		Range	Display Resolution	Units	Osmetech OPTI 1	Osmetech OPTI CCA
Base excess in vitro	BE	-40 - +40	0.1	mmol/L	✓	✓
Base excess in vivo	BEecf	-40 - +40	0.1	mmol/L	✓	✓
Base excess actual	BEact	-40 - +40	0.1	mmol/L		✓
Buffer base	BB	0 - 100	0.1	mmol/L	✓	✓
Actual bicarbonate	HCO_3^-	1 - 200	0.1	mmol/L	✓	✓
Total CO_2	TCO_2	1 - 200	0.1	mmol/L	✓	✓
Standard bicarbonate	$stHCO_3^-$	1 - 200	0.1	mmol/L	✓	✓
Standard pH	stpH	6.5 - 8.0	0.001	pH units	✓	✓
Oxygen saturation	O_2sat	0 - 100	0.1	%	✓	✓
Oxygen content	O_2ct	0 - 56	0.1	vol%	✓	✓
Hydrogen ion concentration	cH^+	1000 - 10	0.1	nmol/L	✓	✓
Alveolar-arterial oxygen partial pressure difference	$AaD\ O_2$	0 - 800	0.1	mmHg	✓	✓
P50	P50	15 - 35	0.1	mmHg		✓
Anion Gap	AnGp	3 - 30	0.1	mmol/L		✓
Normalized Ca++	nCa++	0.1 - 3.0	0.1	mmol/L		✓
Hematocrit, Calculated	Hct(c)	15 - 75	1	PCV%		✓

Data Management			**Osmetech OPTI 1**	**Osmetech OPTI CCA**
Printout	built-in thermoprinter		✓	✓
Serial Interface	1x RS 232, 9-pin SUBMIN D/F	ASCII or ASTM	ASCII only	✓
Infrared Interface	1XIR (Unidirectional or Bi-directional (Osmetech OPTI CCA only))	ASTM		✓

Gas Supply	
Calibration Gas	14 % O_2, 6 % CO_2, balance N_2, max. pressure 140 psi (9.7 bar)

Operating Parameters	
Sample type	Heparinized whole blood, plasma/serum (pH only), Osmetech approved quality control materials
Sample input device	syringe, capillary, microsampler
Sample size	Osmetech OPTI 1 80µL Osmetech OPTI CCA 125µL
Sample input	automatic aspiration
Analysis time	< 2 minutes
Type of measurement	Optical fluorescence and reflectance
Units	conventional, standard international (SI)

Temperature / Humidity	
Ambient temperature	15 °C - 32 °C (60 °F – 90 °F) – Osmetech OPTI 1 10 °C - 32 °C (50 °F – 90 °F) – Osmetech OPTI CCA
Measuring chamber temperature	37 °C ± 0.1 °C (98.6 °F ± 0.18 °F) (Osmetech OPTI 1 & Osmetech OPTI CCA)
Relative humidity	5 - 95 % non-condensing (Osmetech OPTI 1 & Osmetech OPTI
Altitude	CCA) up to 3048 m (10,000 ft)

Electrical Supply	
Mains supply	100 ± 10% VAC to 240 ± 10% VAC
Frequency	50 - 60 Hz
Power consumption	45W max (7W standby)

Overvoltage Category

Category II when connected to a branch circuit

Pollution Degree

Degree 2, normal indoor laboratory environment. Air contains only non-conductive pollutants with occasional condensation.

Classification

Approvals	UL3101-1, CAN/CSA C22.2 NO.1010.1, CE
Mode of Operation	Continuous operation
Laser Classification	This device is a Class 1 laser device according to IEC 60825-1
Explosion protection	The device is not specified for operation inside explosion hazardous areas.

Dimensions / Weight

Height	4.875 inches (12.4 cm)
Width	14.25 inches (36.2 cm)
Depth	4.75 inches (27.8 cm)
Weight	10.5 pounds (4.8 kg) with battery

Acoustic Noise Level

standby	28 dbA
ready	28 dbA
wash/dry	60 dbA
measurement	43 dbA

Principles of Operation

Luminescence is the emission of light energy resulting from "excited" molecules returning to a resting state. When luminescence is initiated by light, it is commonly referred to as fluorescence. When a fluorescent chemical is exposed to light energy of an appropriate "color", electrons in the molecules of the fluorescent chemical are "excited". A very short time later, the electrons return to a resting state and in this process sometimes emit a small amount of light energy. This energy is less than the excitation energy and thus has a different color. That is, the emitted light (fluorescence emission), is red-shifted from the excitation light and is much less intense.

Fluorescent optodes (from **opt**ical electr**odes**) essentially measure the intensity of light emitted from fluorescent dyes. The emitted light is distinguished from excitation light by means of optical filters. Because the excitation light energy is kept constant, the small amount of light that results is changed only by the concentration of the analyte. The concentration of the analyte is determined by the calculation of the difference in fluorescence measured at a known calibration point and fluorescence measured with the unknown concentration of analyte.

The PO_2 optode measurement principle is based upon luminescence, first documented in the 1930's, and commercially utilized to measure blood PO_2 in 1983. The relationship of luminescence to PO_2 is quantified by the Stern-Volmer equation which describes how the fluorescence emission intensity "I" is reduced as the PO_2 "P" is increased. Unlike conventional electrochemical "Clark" PO_2 electrodes, the oxygen optode does not consume oxygen molecules during the measurement.

The pH optode measurement principle is based upon pH-dependent changes of the luminescence of a dye molecule immobilized in the optode. Chemists have used such pH indicator dyes for many years to perform acid-base titrations in turbid media. The relationship of luminescence to pH is quantified by a variant of the Mass-Action Law of chemistry that describes how the fluorescence emission intensity increases as the blood pH is increased above the dye's characteristic pKa. pH optodes do not need a reference electrode to measure pH; however, they exhibit a small sensitivity to the ionic strength of the sample being measured.

The PCO_2 optode measurement principle is based upon placing a pH optode behind an ion-impermeable membrane, just as conventional PCO_2 blood gas electrodes employ the Severinghaus CO_2 electrode construction. As such, PCO_2 optodes suffer from non-selective interference from volatile acids and bases in blood just as conventional PCO_2 electrodes.

During the measurement, light originating from lamps in the analyzer is passed through optical filters so that specific colors are transmitted to the sensors, causing them to emit fluorescence. The intensity of this emitted light depends upon the partial pressure of oxygen (PO_2), carbon dioxide (PO_2) or hydrogen ion concentration (pH) of the blood in direct contact with the sensors, as described above. The light emitted by the fluorescent sensors passes through lenses and additional optical components. A filter is used to isolate specific colors of interest from this returning light for measurement by a light detector.

The Na, K, Ca^{++} and Cl^{-} ion optodes are based upon the principle of Ion Selective Electrodes (ISEs). The optodes use ion selective recognition elements (ionophores) similar to those used in ISE's, however the ionophores are linked to fluorescent dyes instead of electrodes. These types of dyes have been used since the 1970s to visualize and quantify cellular ion levels in fluorescence microscopy and cell counters. As the ion concentration increases, these ionophores bind larger amounts of ions and cause the fluorescence intensity to increase or decrease, depending on the particular ion. Like the pH optode, the ion optodes do not need a reference electrode, however they do exhibit a small pH sensitivity that is automatically compensated in the Osmetech OPTI using the measured pH.

The glucose optode measurement is based on the enzymatic oxidation of glucose

$$\text{glucose} + O_2 \xrightarrow[\text{glucose oxidase}]{} \text{gluconic acid} + H_2O_2$$

The sensor is constructed of an enzyme layer over an oxygen sensor. As a sample containing glucose contacts the sensor this oxidation of the glucose consumes the oxygen locally present in the sensor.
This decrease in oxygen is detected in the same manner (luminescence quenching) as described for the PO_2 optode. The amount of glucose is determined to be proporational to the rate at which the oxygen is consumed.

The measurement of total Hemoglobin (ctHb) and oxygen saturation (SO_2) uses the well-established principle of optical reflectance. Red and infrared light a three wavelengths is directed at whole, non-hemolyzed blood within a precisely defined part of the cassette over the O_2 optode. The photons are partially absorbed and reflected by erythrocytes in a manner proportional to hemoglobin level; at low hemoglobin levels the unabsorbed photons strike the O_2 optode's pink overcoat and are reflected back up through the blood a second time.
A portion of the reflected light exits the top of the cassette and is measured by a detector in the instrument. The infrared wavelengths are selected for the hemoglobin measurement because they are largely independent of SO_2, that is, the predominate forms of adult and fetal hemoglobin absorb similarly within the 750 – 850 nm wavelength range.

The red wavelength is utilized for the SO2 measurement because it is much more strongly absorbed by deoxyhemoglobin than all other hemoglobins, and is picked close to the isobestic point for oxy- and carboxyhemglobin. Maintaining high shear force just prior to measurement minimizes sensitivity to erythrocyte aggregation (rouleau formation).

The optical signal of the detectors is converted by the microprocessor to a numerical readout in conventional units of measure and displayed on the front of the device. Other values commonly used for the assessment of oxygen and acid-base status are calculated from these measured values.

The entire sample path of the Osmetech OPTI cassette is filled with storage buffer to keep the sensors stable during storage. In addition, the cassette pouch is filled with a CO_2 atmosphere, which keeps the pH of the storage buffer stable.

The cassette not only contains the sensors but also houses a distribution valve (cassette valve), the sample fill port, an input/output port (I/O port), a reservoir and a vent.

The function of the I/O port is to connect the cassette to the peristaltic pump allowing sample aspiration and calibration gas to flow through the cassette.

The storage buffer in the reservoir ensures stability over the shelf life of the cassette.

The distribution valve has 2 functions: its hollow body serves as a waste container, referred to as “waste”, holding storage buffer and OPTI-trol. In addition, the cassette valve incorporates small channels, called links that connect the sensor channel, the fill port, the vent and the I/O port in different combinations. These different connections are achieved by turning the cassette valve to different positions. Each valve position has an assigned number. An unused cassette is set to position 0, the home position. The diagram on page 2-9 shows the valve positions and the connections for each position. E.g., position 2 connects the fill port via the valve link to the sensor channel and the reservoir to the I/O port.

The Osmetech OPTI 1 and Osmetech OPTI CCA analyzers are microprocessor-based instruments measuring optical fluorescence. The disposable, single-use cassette contains all the elements needed for calibration, sample measurement and waste containment. After reading the calibration information specific to a cassette into the instrument by 'swiping' the cassette package through a convenient bar code reader, the cassette is placed in the measurement chamber. While the analyzer warms the cassette to 37.0 ± 0.1 °C, the cassette valve is turned to position 5. In this position, the I/O port is connected to the vent allowing the pump to purge calibration gas. At the same time, readings are taken from all sensors to ensure proper functioning. In addition, the fluid light gates L1, L2 and L3 are calibrated.

Then the valve turns to position 1 which connects the I/O port to the reservoir and the cassette sensors to the vent via the waste. The pump starts pushing the storage buffer into the waste. L1 and L2 monitor the movement of the buffer and the pump rate. After the buffer is pushed into the waste, the valve turns to position 4, which connects the I/O port to the reservoir and the sensors directly to the vent. The pump first purges the cassette with calibration gas, then slows down during the actual gas calibration passing the gravimetrically prepared gas mix across the sensors. The pH sensor is calibrated via the precision storage buffer. Calibration is completed when stable readings of all sensors are obtained. The calibration process lasts from 15 to 80 seconds.

After calibration verification, the cassette valve turns to position 8 closing off all ports. The instrument now waits for aspiration of sample fluid.

After pressing the Enter key, the valve turns to position 2, which connects the fill port to the sensor channel and the reservoir to the I/O port via waste. The pump starts aspirating the sample. During aspiration, the sample light gates L1 and L2 check for sample type (blood or clear fluid), bubbles and sufficient sample volume.

Once the sample has been aspirated successfully, the valve turns again to position 4. After a short warm-up period, readings are taken from all 3 sensors. Once stable readings are obtained, the valve turns to position 8 closing off all ports. The results are calculated and the cassette is ready for disposal.

In case of an OPTI-trol measurement (Osmetech OPTI 1 only), the user has the option of terminating the measurement or introducing a subsequent blood sample. If a blood sample is introduced, the OPTI-trol is purged into the waste and the blood sample is aspirated and analyzed.

Fluidics Block Diagram

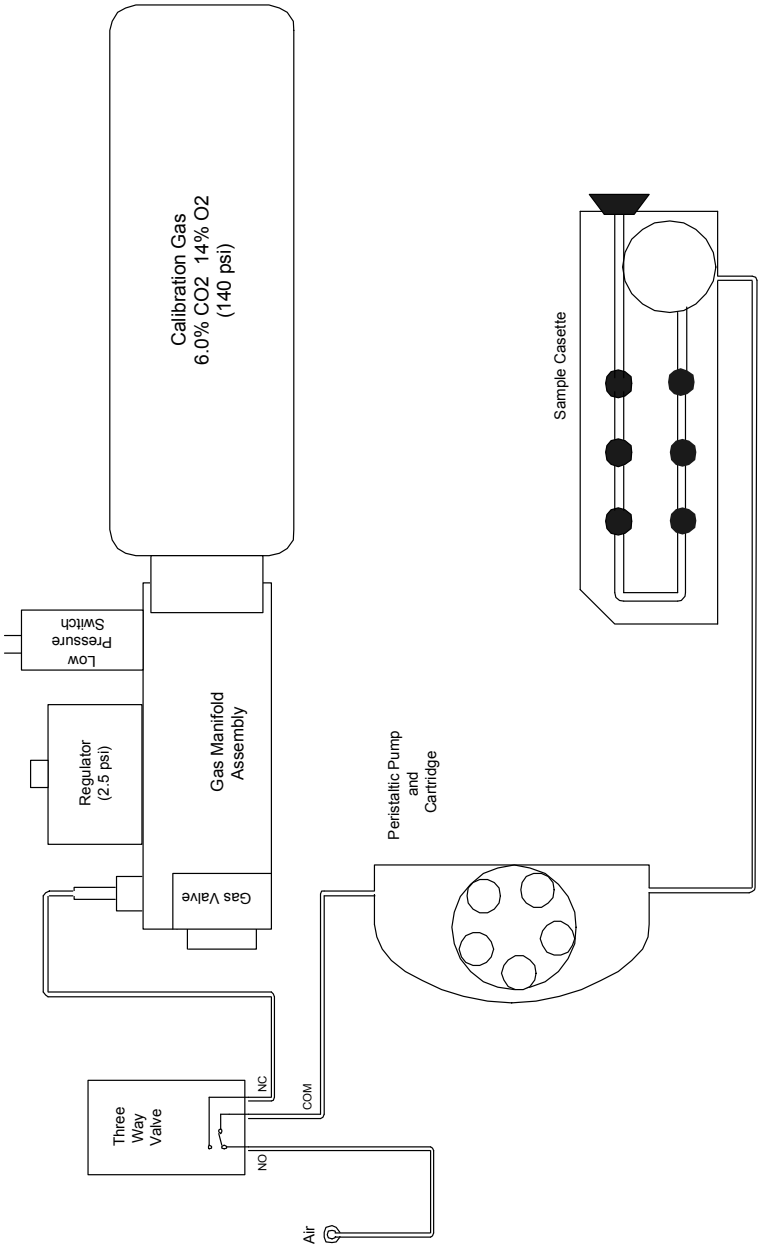


Fig. 2-1: Fluidics Block Diagram

Osmetech OPTI Cassette

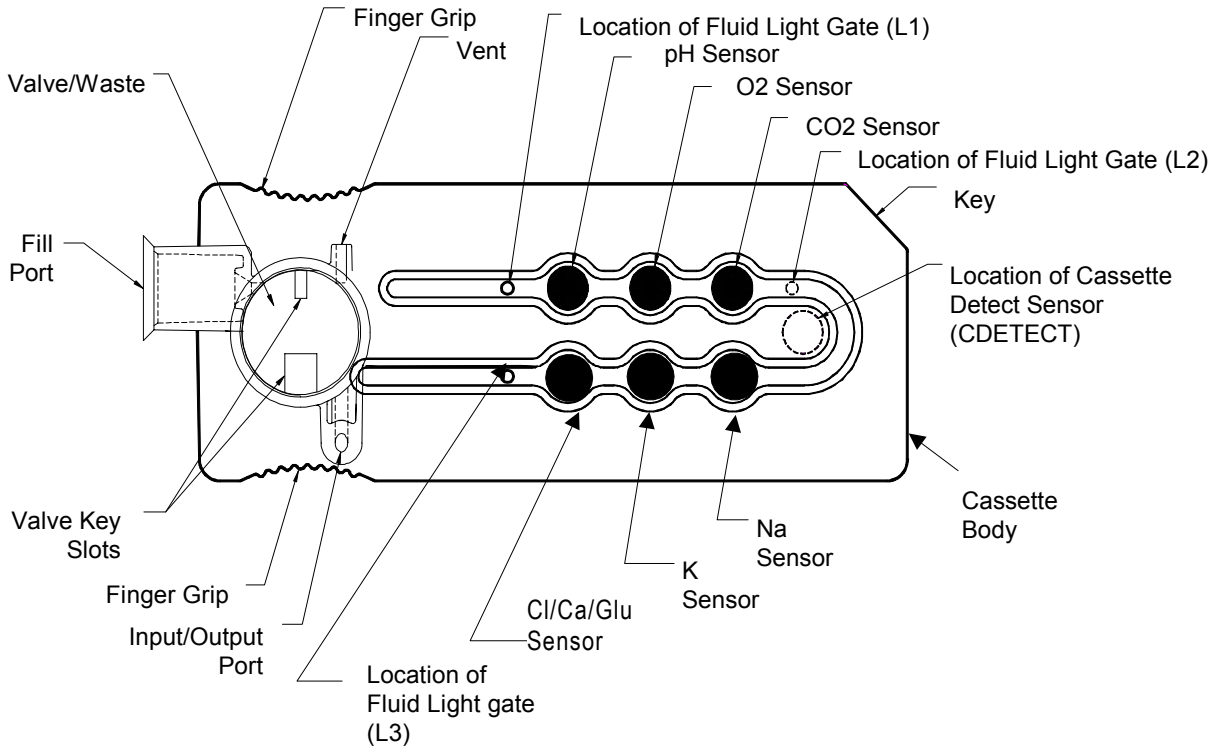


Fig. 2-2: Osmetech OPTI Cassette

Osmetech OPTI Cassette Valve Positions

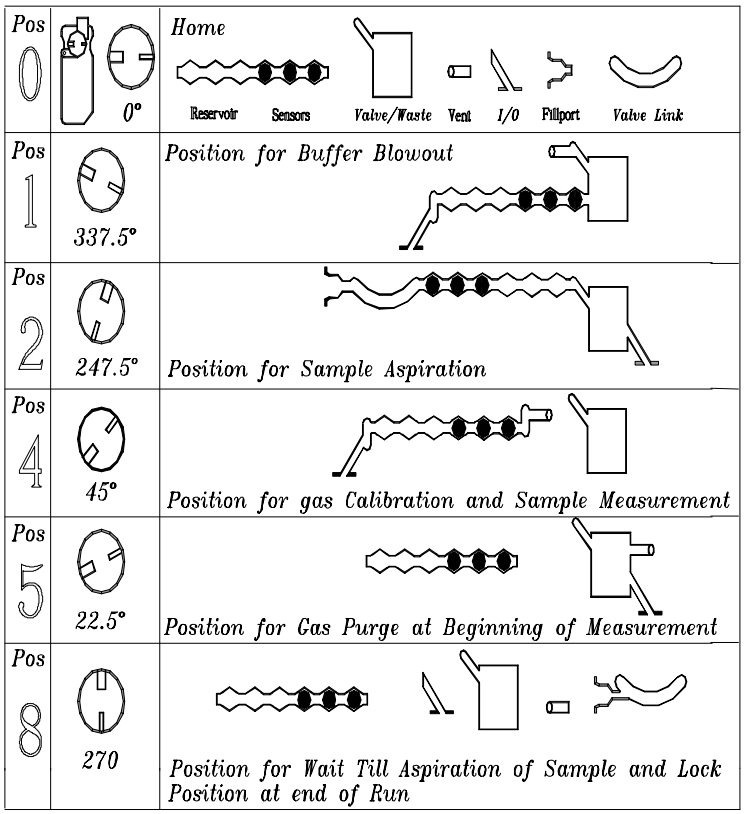


Fig. 2-3: Osmetech OPTI Cassette Valve Positions

Assemblies

The Osmetech OPTI consists of several major components and assemblies that control the operation of the analyzer. A brief function description of the assemblies is provided below.

Valves

Valve	The gas valve module controls the delivery of the internal calibration gas. The gas valve module incorporates a pressure regulator, pressure sensor, gas valve and a three-way valve.
Vdrive	The valve drive assembly is a stepper motor that controls the positioning of the cassette valve.
Pump	The peristaltic pump assembly is a stepper motor and pump cartridge that provides for the pump flow used to transport sample and calibrator material through the cassette.

Modular Components

- The sample measurement chamber (SMC) assembly provides thermostated heating control of the measuring chamber at 37 °C ± 0.1 °C (98.6 °F ± 0.18 °F).
- The optics module is a microprocessor-based assembly that houses the optics detectors, preamplifiers and processing circuitry for optode sensor signals.
- The main board includes the main microprocessor, RAM and EPROM memory and control circuitry for the LCD display, keyboard, printer motors, barcode and serial interface.
- The Osmetech OPTI Cassette contains the optode sensor used to measure the sample and also includes the reservoir for reagent and sample waste.
- The Osmetech OPTI CCA (only) SMC cover provides optics and processing circuitry for ctHb/SO_2 measurement.
- A minimal amount of tubing is used in the Osmetech OPTI system.
- Storage compartment.
- Liquid crystal display, 2 lines x 24 characters per line.
- Keyboard with numeric keys, ← and → keys, Enter and Esc keys.
- Thermoprinter.
- Serial RS 232 C or Infrared (Osmetech OPTI CCA only) - interface
- Barcode reader

Software Structure

The Osmetech OPTI software is designed to provide a simple user interface organized in a menu fashion. The operator may select a menu function by using the ← and → keys to move to the desired menu selection.
The menu function to be selected will be blinking. Pressing the Enter key will select the desired menu item.

The following system software menus are provided in flow chart format and show the software menu structure:

Main Menu

Sampling Menu

Run Menu

Data Menu

Setup Menu

Diagnostic Menu

QC - Range Setup Menu

Main Menu – Osmetech OPTI 1

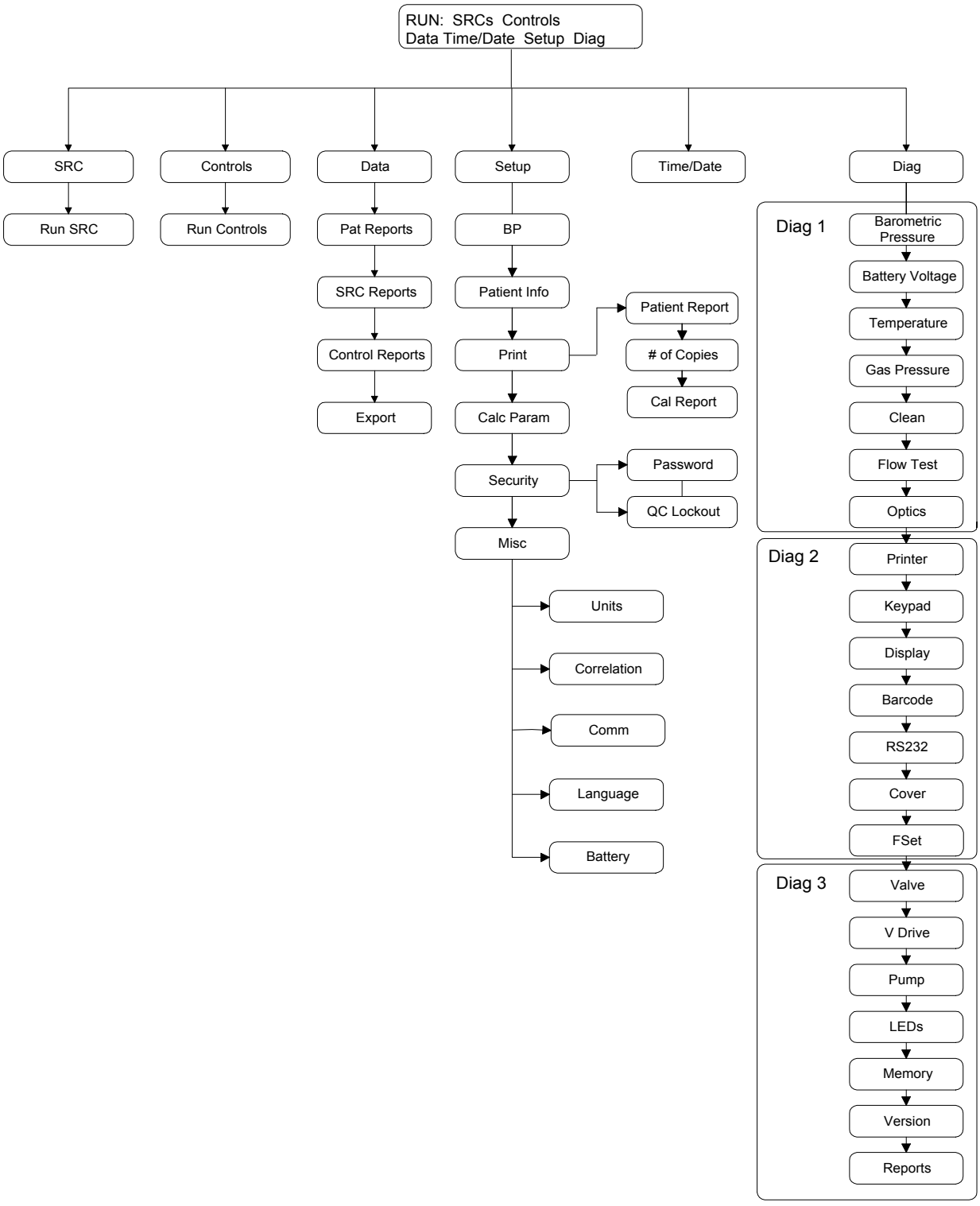


Fig. 2-4: Main Menu

Sampling Menu – Osmetech OPTI 1

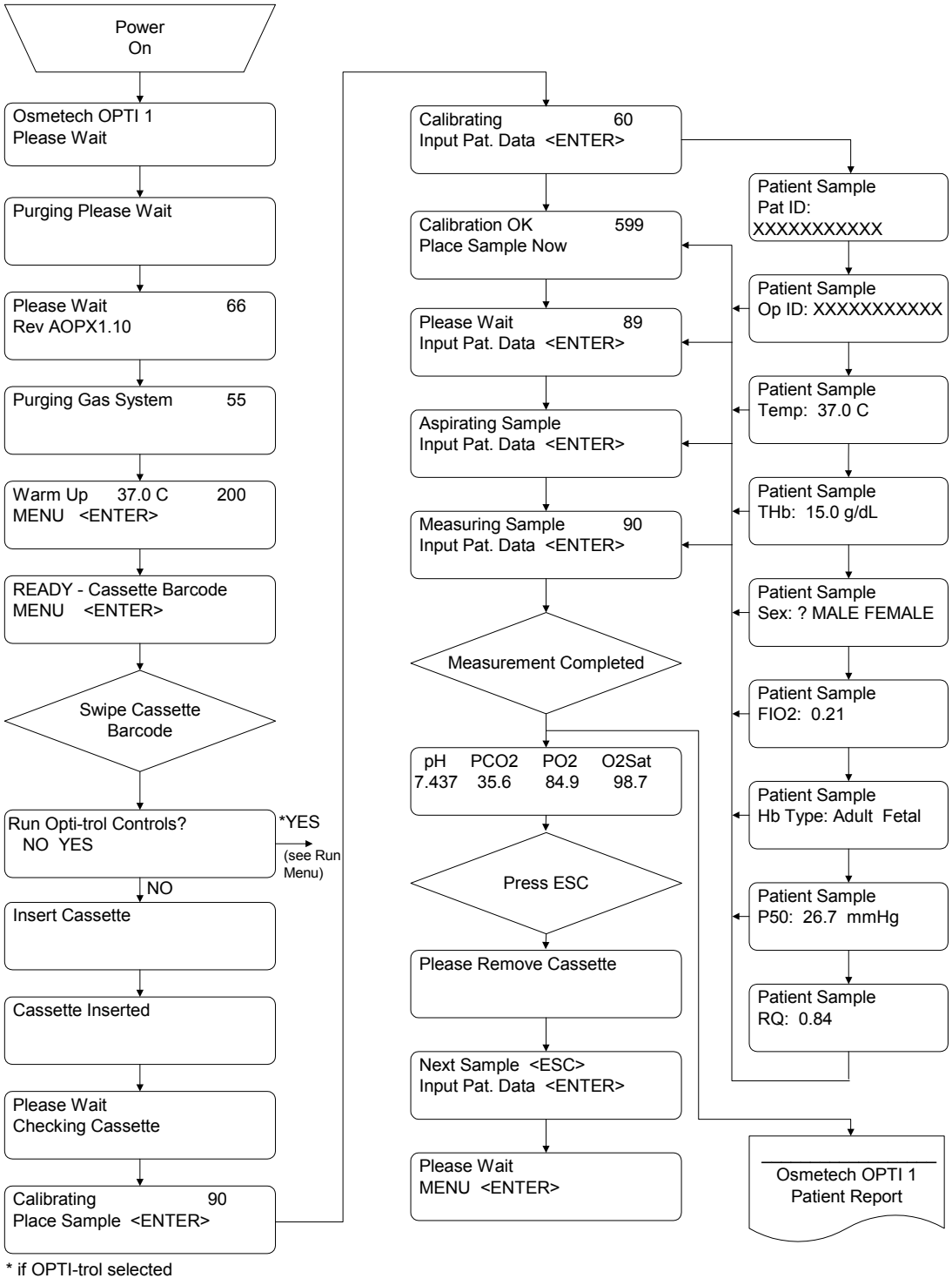


Fig. 2-5: Sampling-Menu

Run Menu – Osmetech OPTI 1

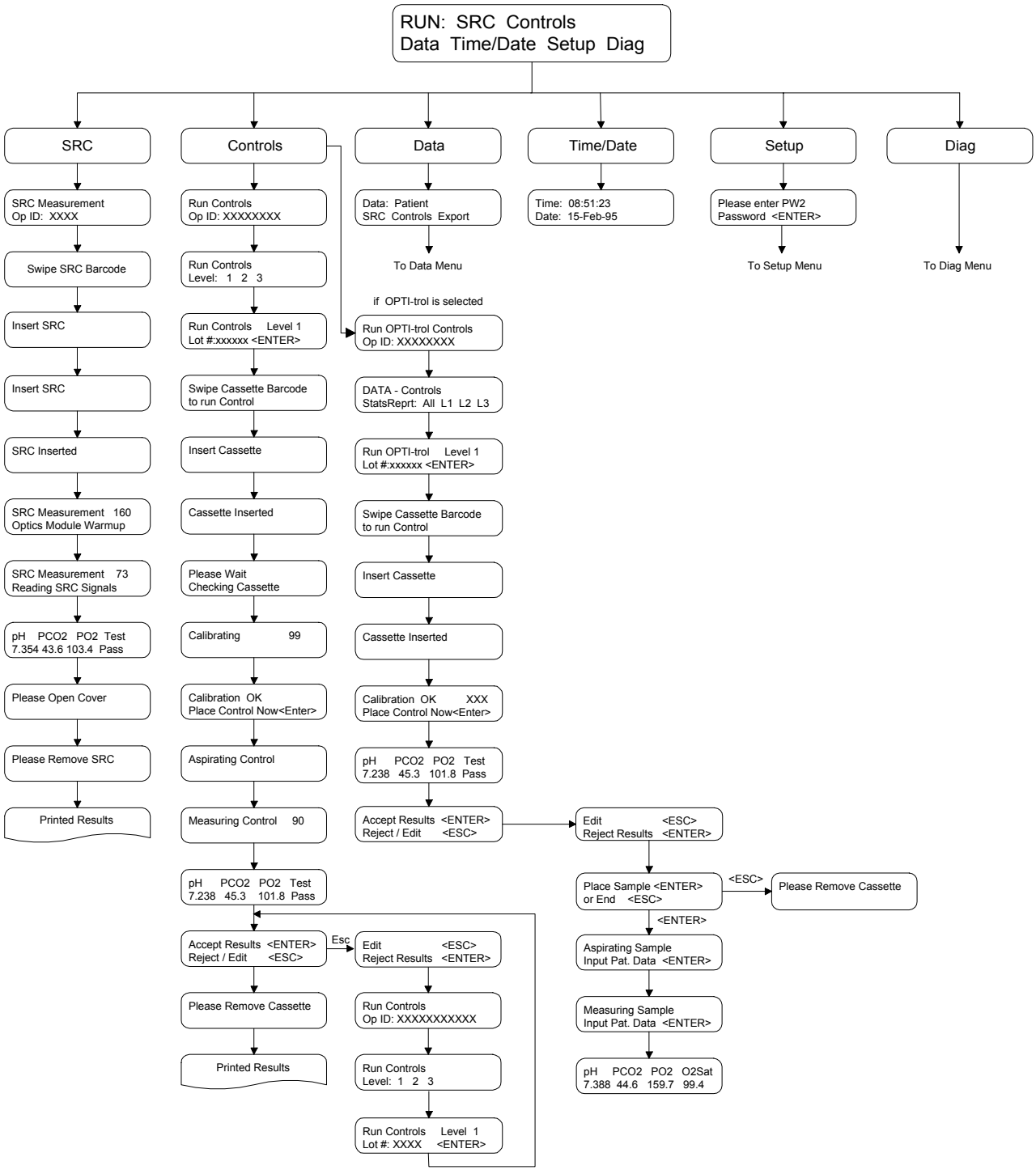


Fig. 2-6: Run Menu

Data Menu – Osmetech OPTI 1

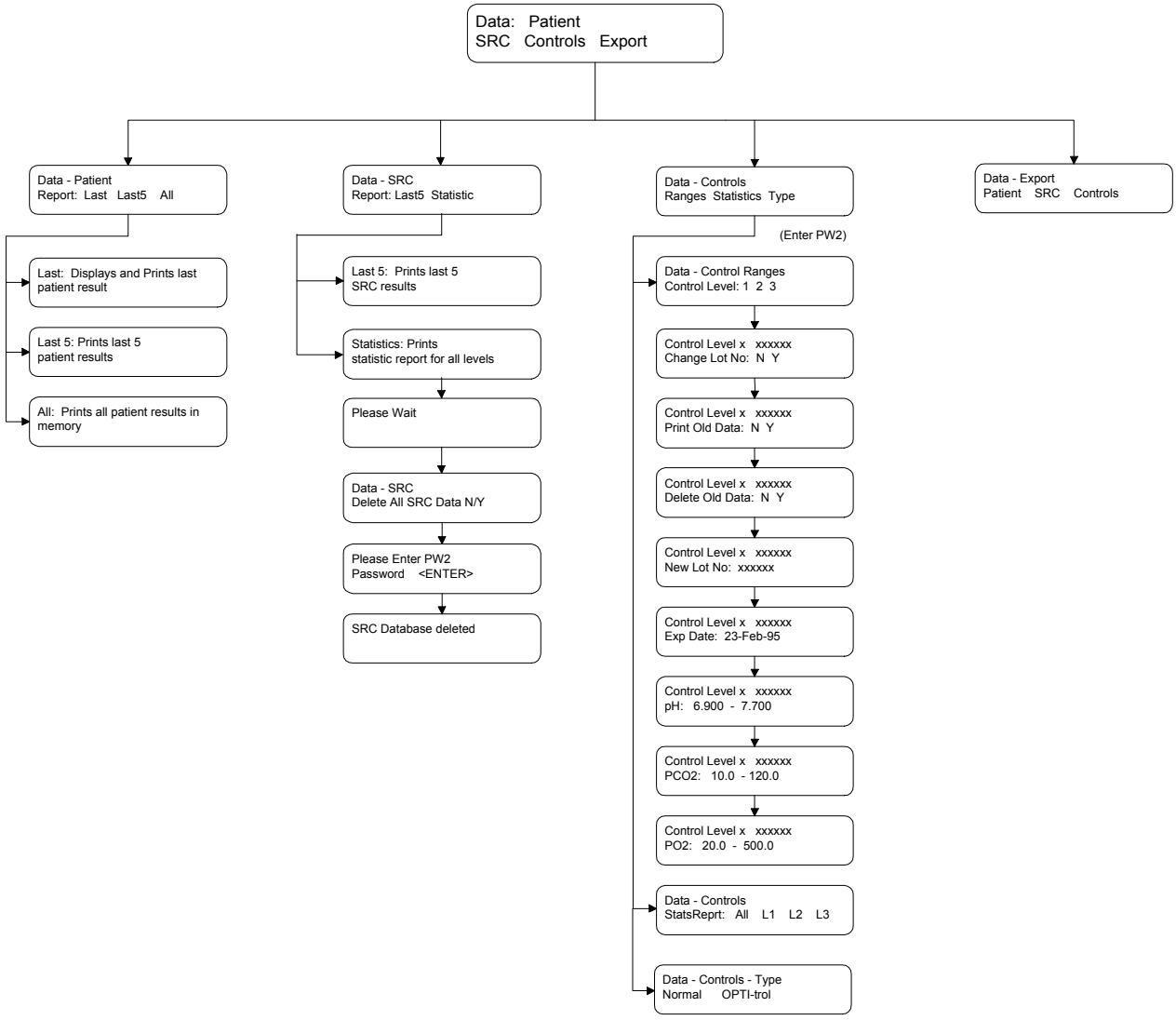

Data: Patient
SRC Controls Export
Data - Patient
Report: Last Last5 All
Last: Displays and Prints last patient result
Last 5: Prints last 5 patient results
All: Prints all patient results in memory
Data - SRC
Report: Last5 Statistic
Last 5: Prints last 5 SRC results
Statistics: Prints statistic report for all levels
Please Wait
Data - SRC
Delete All SRC Data N/Y
Please Enter PW2
Password <ENTER>
SRC Database deleted
Data - Controls
Ranges Statistics Type
(Enter PW2)
Data - Control Ranges
Control Level: 1 2 3
Control Level x xxxxxx
Change Lot No: N Y
Control Level x xxxxxx
Print Old Data: N Y
Control Level x xxxxxx
Delete Old Data: N Y
Control Level x xxxxxx
New Lot No: xxxxxx
Control Level x xxxxxx
Exp Date: 23-Feb-95
Control Level x xxxxxx
pH: 6.900 - 7.700
Control Level x xxxxxx
PCO2: 10.0 - 120.0
Control Level x xxxxxx
PO2: 20.0 - 500.0
Data - Controls
StatsReprt: All L1 L2 L3
Data - Controls - Type
Normal OPTI-trol
Data - Export
Patient SRC Controls

Fig. 2-7: Data Menu

Setup Menu – Osmetech OPTI 1

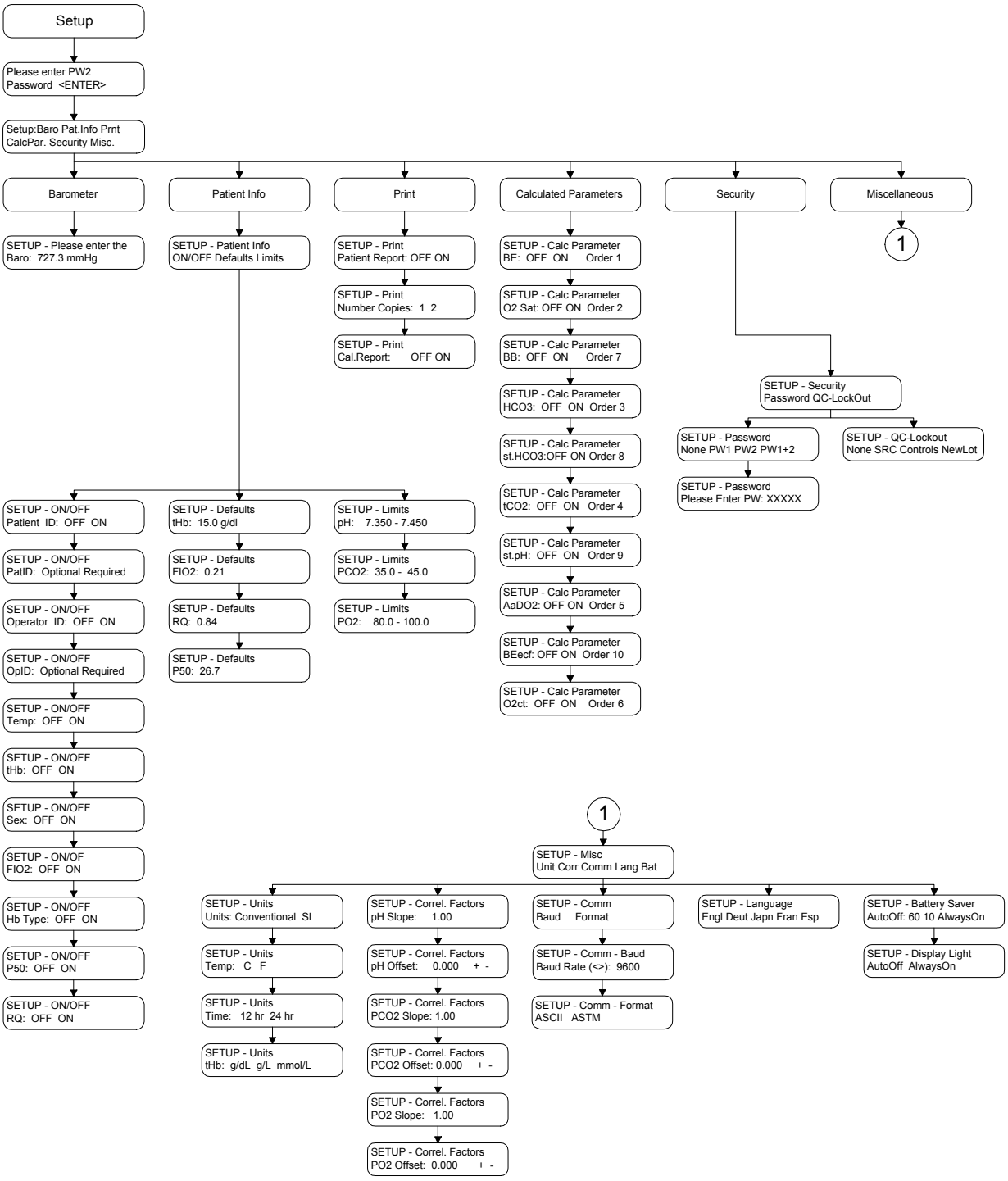


Fig. 2-8: Setup Menu

Diagnostic Menu – Osmetech OPTI 1

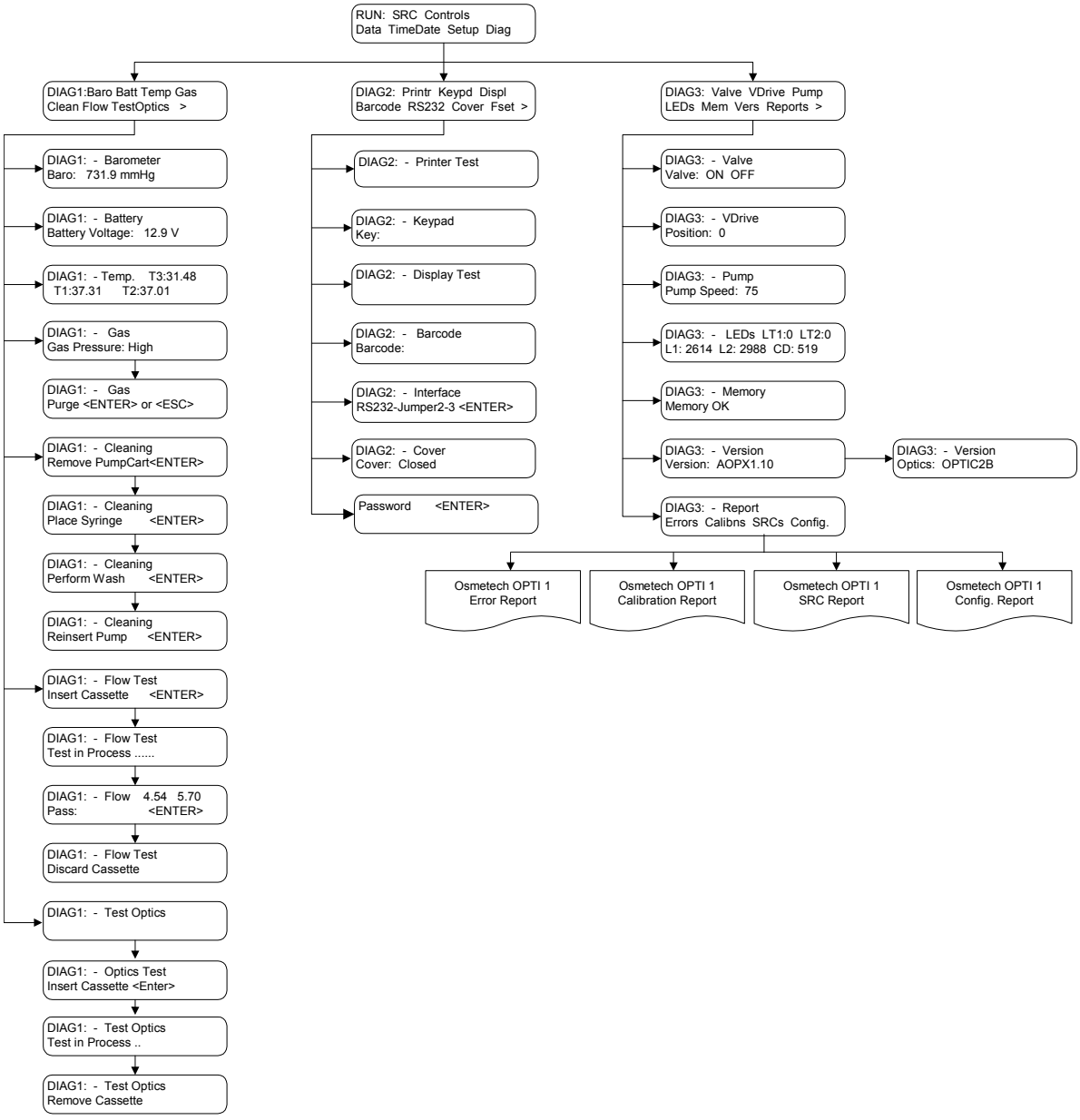


Fig. 2-9: Diagnostic Menu

QC-Range Setup – Osmetech OPTI 1

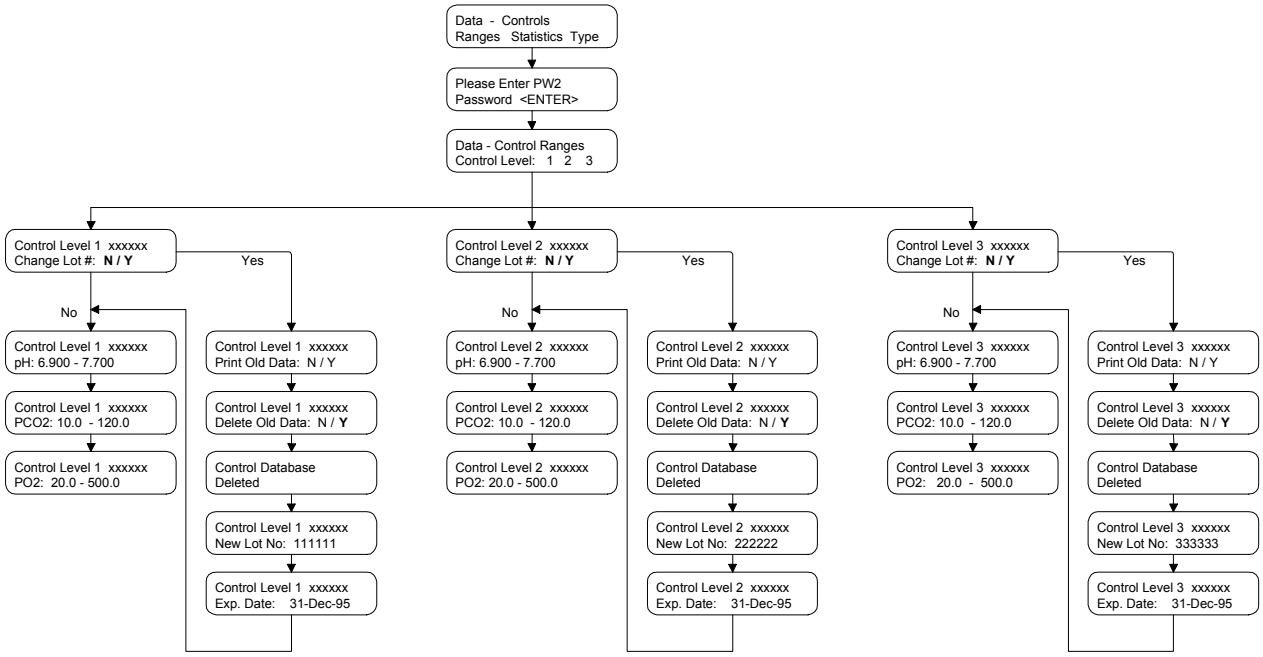


Fig. 2-10: QC Ranges Setup

Main Menu – Osmetech OPTI CCA

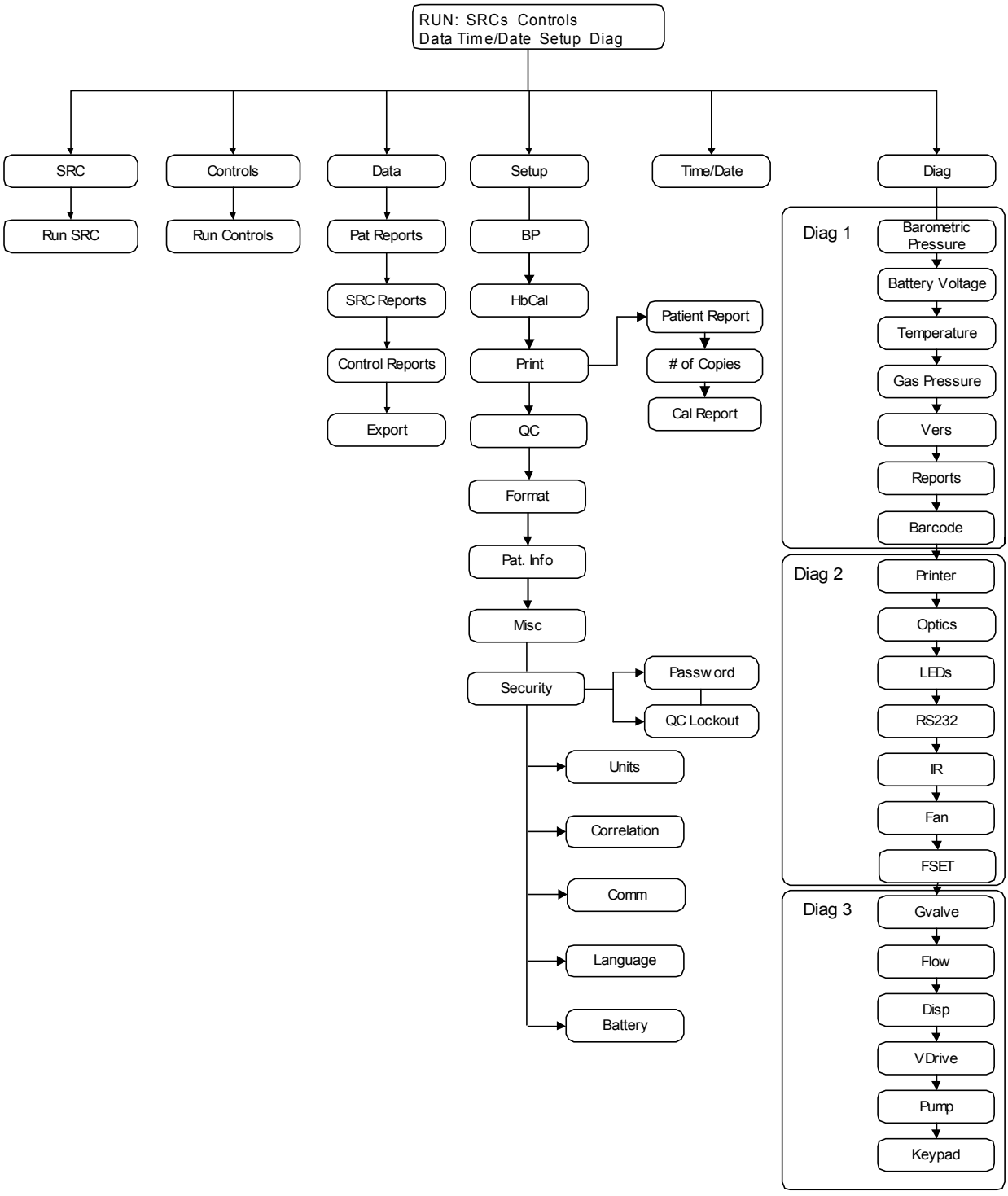
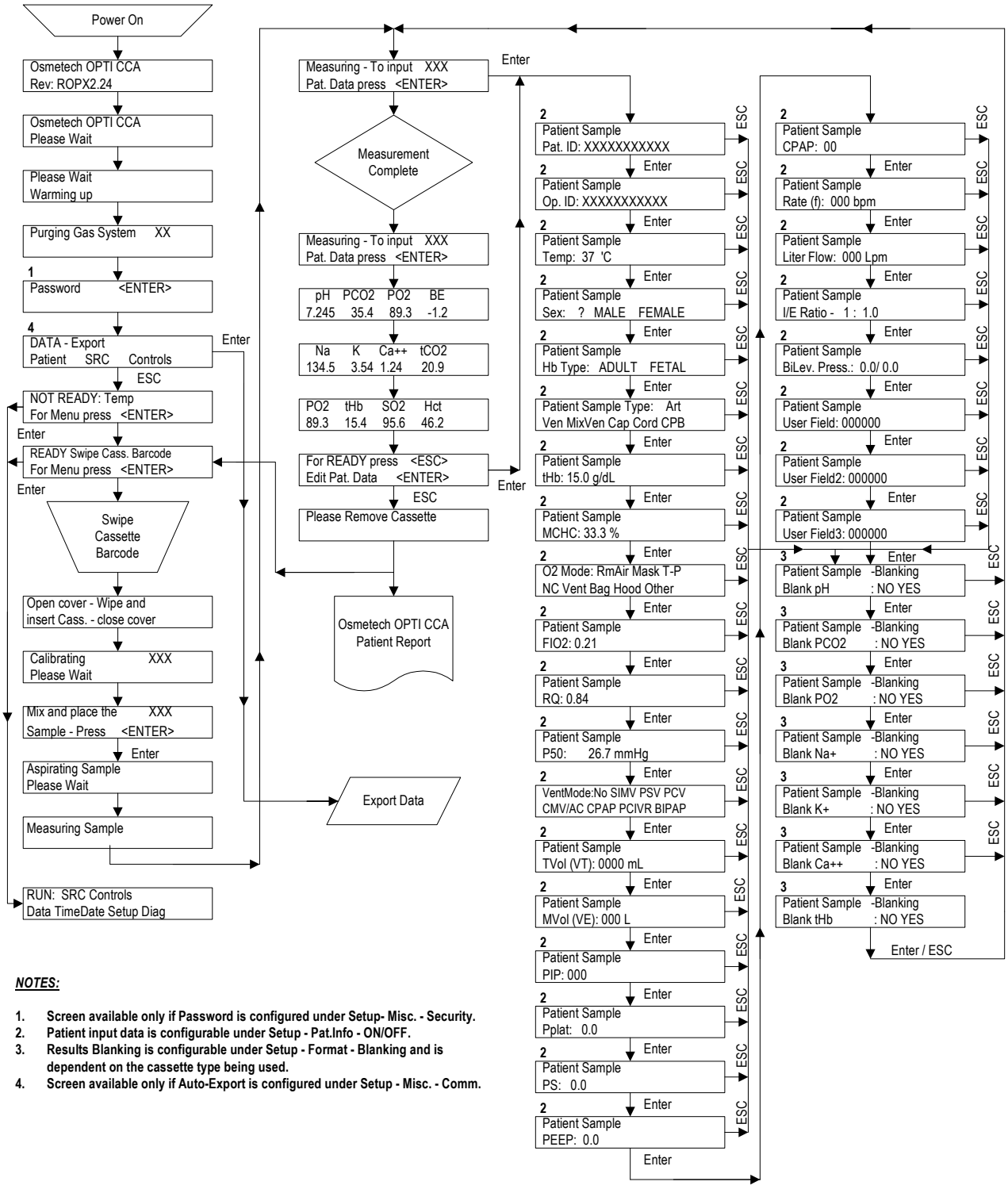


Fig. 2-11: Main Menu

Sampling Menu – Osmetech OPTI CCA



NOTES:

1. **Screen available only if Password is configured under Setup- Misc. - Security.**
2. **Patient input data is configurable under Setup - Pat.Info - ON/OFF.**
3. **Results Blanking is configurable under Setup - Format - Blanking and is dependent on the cassette type being used.**
4. **Screen available only if Auto-Export is configured under Setup - Misc. - Comm.**

Fig. 2-12: Sampling Menu

Run Menu – Osmetech OPTI CCA

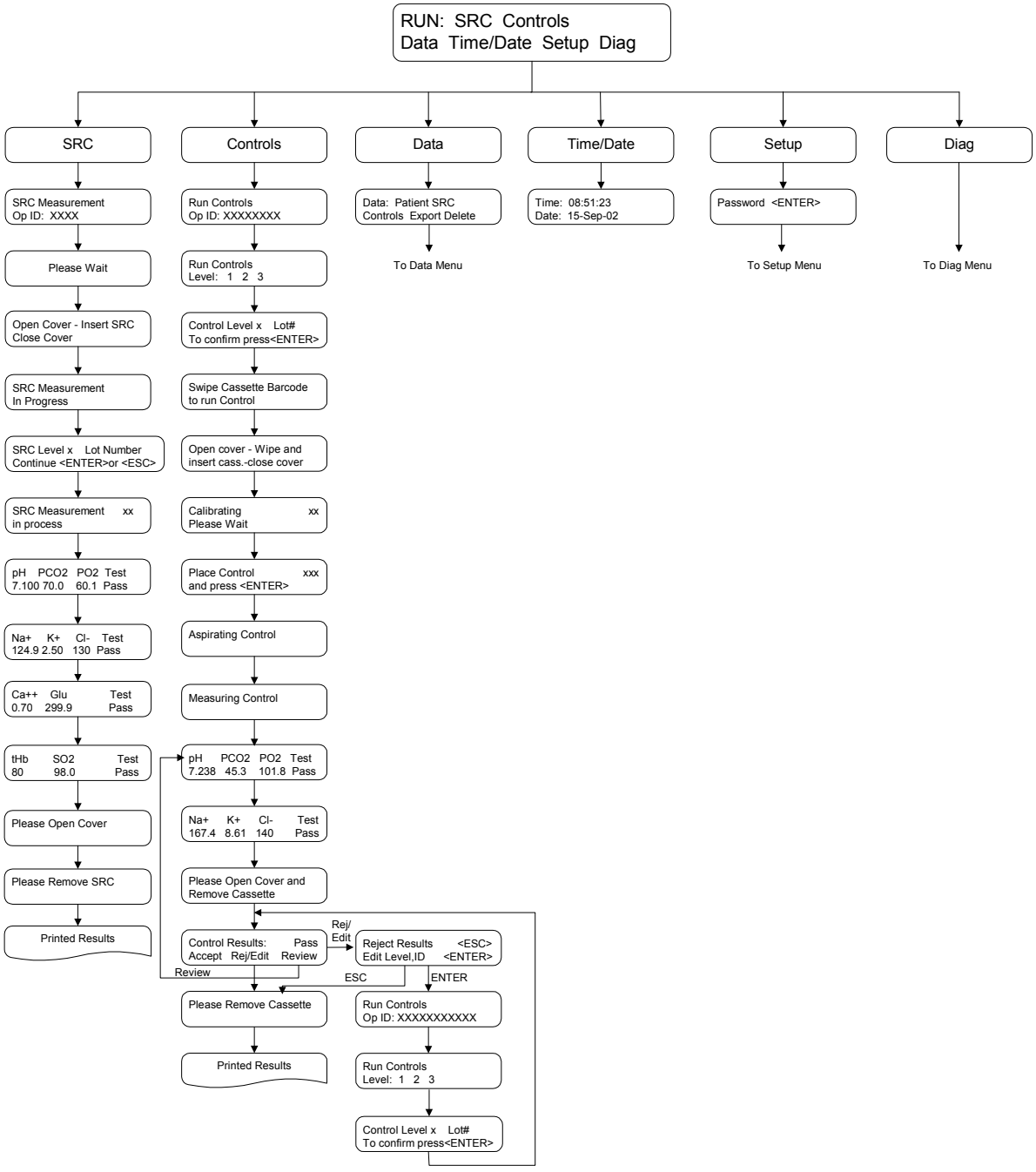


Fig. 2-13: Run Menu

Data Menu – Osmetech OPTI CCA

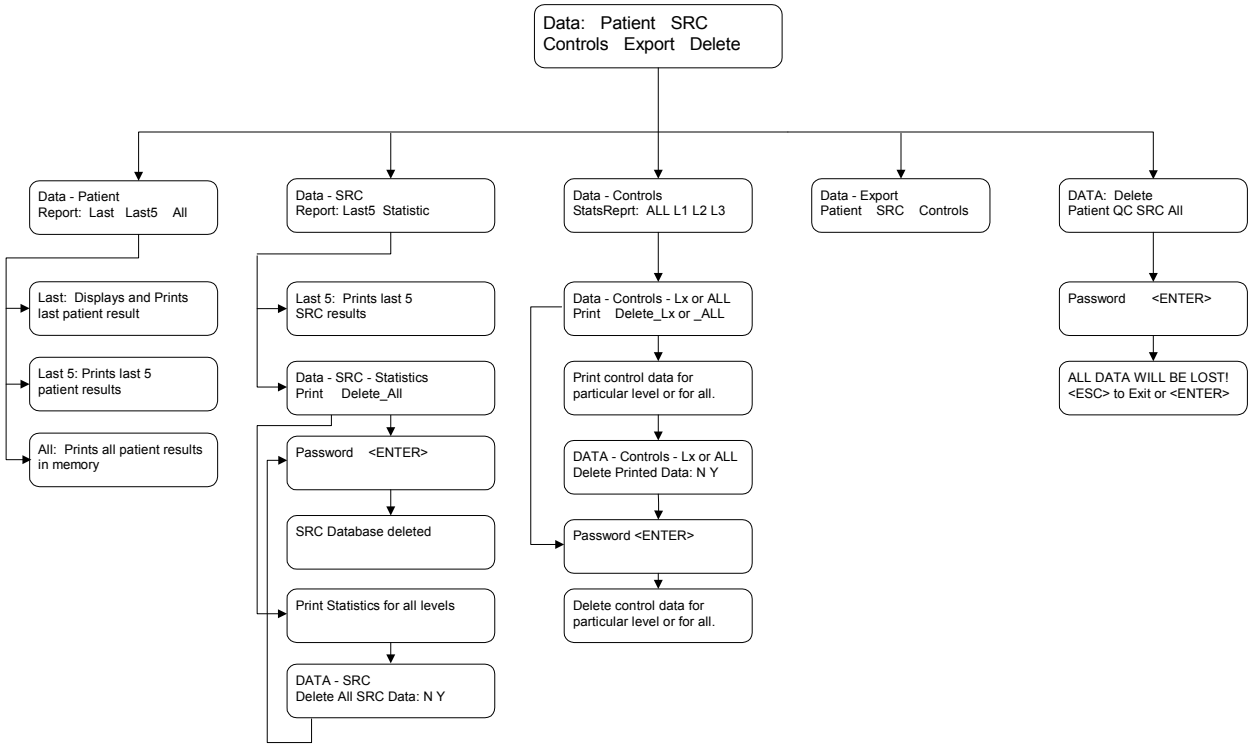

Data: Patient SRC
Controls Export Delete
Data - Patient
Report: Last Last5 All
Last: Displays and Prints last patient result
Last 5: Prints last 5 patient results
All: Prints all patient results in memory
Data - SRC
Report: Last5 Statistic
Last 5: Prints last 5 SRC results
Data - SRC - Statistics
Print Delete_All
Password <ENTER>
SRC Database deleted
Print Statistics for all levels
DATA - SRC
Delete All SRC Data: N Y
Data - Controls
StatsReprt: ALL L1 L2 L3
Data - Controls - Lx or ALL
Print Delete_Lx or _ALL
Print control data for particular level or for all.
DATA - Controls - Lx or ALL
Delete Printed Data: N Y
Password <ENTER>
Delete control data for particular level or for all.
Data - Export
Patient SRC Controls
DATA: Delete
Patient QC SRC All
Password <ENTER>
ALL DATA WILL BE LOST!
<ESC> to Exit or <ENTER>

Fig. 2-14: Data Menu

Setup Menu – Osmetech OPTI CCA

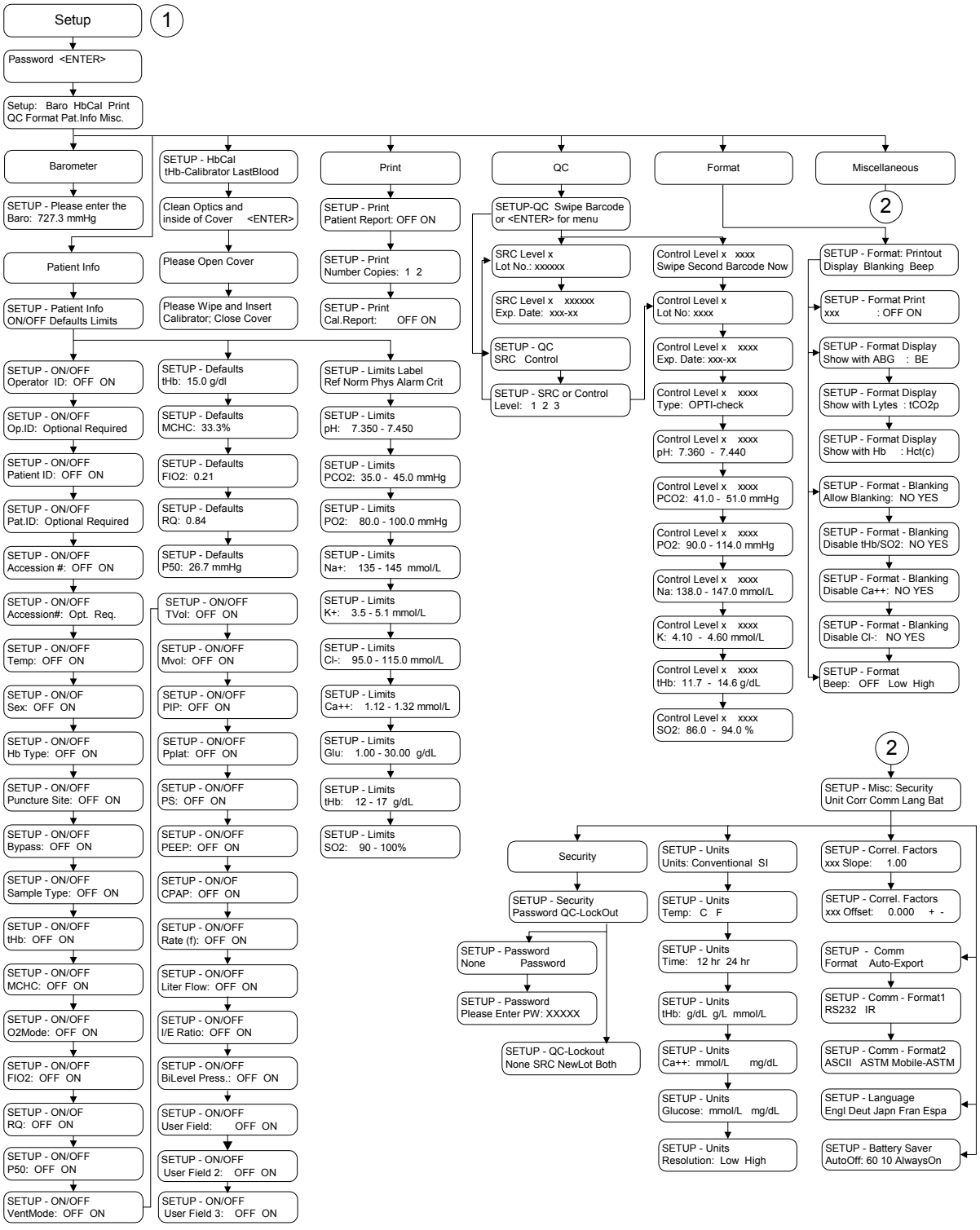

Setup
1
Password <ENTER>
Setup: Baro HbCal Print QC Format Pat.Info Misc.
Barometer
SETUP - Please enter the Baro: 727.3 mmHg
Patient Info
SETUP - Patient Info ON/OFF Defaults Limits
SETUP - ON/OFF Operator ID: OFF ON
SETUP - ON/OFF Op.ID: Optional Required
SETUP - ON/OFF Patient ID: OFF ON
SETUP - ON/OFF Pat.ID: Optional Required
SETUP - ON/OFF Accession #: OFF ON
SETUP - ON/OFF Accession#: Opt. Req.
SETUP - ON/OFF Temp: OFF ON
SETUP - ON/OF Sex: OFF ON
SETUP - ON/OFF Hb Type: OFF ON
SETUP - ON/OFF Puncture Site: OFF ON
SETUP - ON/OFF Bypass: OFF ON
SETUP - ON/OFF Sample Type: OFF ON
SETUP - ON/OFF tHb: OFF ON
SETUP - ON/OFF MCHC: OFF ON
SETUP - ON/OFF O2Mode: OFF ON
SETUP - ON/OFF FIO2: OFF ON
SETUP - ON/OF RQ: OFF ON
SETUP - ON/OFF P50: OFF ON
SETUP - ON/OFF VentMode: OFF ON
SETUP - HbCal tHb-Calibrator LastBlood
Clean Optics and inside of Cover <ENTER>
Please Open Cover
Please Wipe and Insert Calibrator; Close Cover
SETUP - Defaults tHb: 15.0 g/dl
SETUP - Defaults MCHC: 33.3%
SETUP - Defaults FIO2: 0.21
SETUP - Defaults RQ: 0.84
SETUP - Defaults P50: 26.7 mmHg
SETUP - ON/OFF TVol: OFF ON
SETUP - ON/OFF Mvol: OFF ON
SETUP - ON/OFF PIP: OFF ON
SETUP - ON/OFF Pplat: OFF ON
SETUP - ON/OFF PS: OFF ON
SETUP - ON/OFF PEEP: OFF ON
SETUP - ON/OF CPAP: OFF ON
SETUP - ON/OFF Rate (f): OFF ON
SETUP - ON/OFF Liter Flow: OFF ON
SETUP - ON/OFF I/E Ratio: OFF ON
SETUP - ON/OFF BiLevel Press.: OFF ON
SETUP - ON/OFF User Field: OFF ON
SETUP - ON/OFF User Field 2: OFF ON
SETUP - ON/OFF User Field 3: OFF ON
Print
SETUP - Print Patient Report: OFF ON
SETUP - Print Number Copies: 1 2
SETUP - Print Cal.Report: OFF ON
SETUP - Limits Label Ref Norm Phys Alarm Crit
SETUP - Limits pH: 7.350 - 7.450
SETUP - Limits PCO2: 35.0 - 45.0 mmHg
SETUP - Limits PO2: 80.0 - 100.0 mmHg
SETUP - Limits Na+: 135 - 145 mmol/L
SETUP - Limits K+: 3.5 - 5.1 mmol/L
SETUP - Limits Cl-: 95.0 - 115.0 mmol/L
SETUP - Limits Ca++: 1.12 - 1.32 mmol/L
SETUP - Limits Glu: 1.00 - 30.00 g/dL
SETUP - Limits tHb: 12 - 17 g/dL
SETUP - Limits SO2: 90 - 100%
QC
SETUP-QC Swipe Barcode or <ENTER> for menu
SRC Level x Lot No.: xxxxxx
SRC Level x xxxxxx Exp. Date: xxx-xx
SETUP - QC SRC Control
SETUP - SRC or Control Level: 1 2 3
Format
Control Level x xxxx Swipe Second Barcode Now
Control Level x Lot No: xxxx
Control Level x xxxx Exp. Date: xxx-xx
Control Level x xxxx Type: OPTI-check
Control Level x xxxx pH: 7.360 - 7.440
Control Level x xxxx PCO2: 41.0 - 51.0 mmHg
Control Level x xxxx PO2: 90.0 - 114.0 mmHg
Control Level x xxxx Na: 138.0 - 147.0 mmol/L
Control Level x xxxx K: 4.10 - 4.60 mmol/L
Control Level x xxxx tHb: 11.7 - 14.6 g/dL
Control Level x xxxx SO2: 86.0 - 94.0 %
Miscellaneous
2
SETUP - Format: Printout Display Blanking Beep
SETUP - Format Print xxx : OFF ON
SETUP - Format Display Show with ABG : BE
SETUP - Format Display Show with Lytes : tCO2p
SETUP - Format Display Show with Hb : Hct(c)
SETUP - Format - Blanking Allow Blanking: NO YES
SETUP - Format - Blanking Disable tHb/SO2: NO YES
SETUP - Format - Blanking Disable Ca++: NO YES
SETUP - Format - Blanking Disable Cl-: NO YES
SETUP - Format Beep: OFF Low High
2
SETUP - Misc: Security Unit Corr Comm Lang Bat
Security
SETUP - Security Password QC-LockOut
SETUP - Password None Password
SETUP - Password Please Enter PW: XXXXX
SETUP - QC-Lockout None SRC NewLot Both
SETUP - Units Units: Conventional SI
SETUP - Units Temp: C F
SETUP - Units Time: 12 hr 24 hr
SETUP - Units tHb: g/dL g/L mmol/L
SETUP - Units Ca++: mmol/L mg/dL
SETUP - Units Glucose: mmol/L mg/dL
SETUP - Units Resolution: Low High
SETUP - Correl. Factors xxx Slope: 1.00
SETUP - Correl. Factors xxx Offset: 0.000 + -
SETUP - Comm Format Auto-Export
SETUP - Comm - Format1 RS232 IR
SETUP - Comm - Format2 ASCII ASTM Mobile-ASTM
SETUP - Language Engl Deut Japn Fran Espa
SETUP - Battery Saver AutoOff: 60 10 AlwaysOn

Fig. 2-15: Setup Menu

Diagnostic Menu – Osmetech OPTI CCA

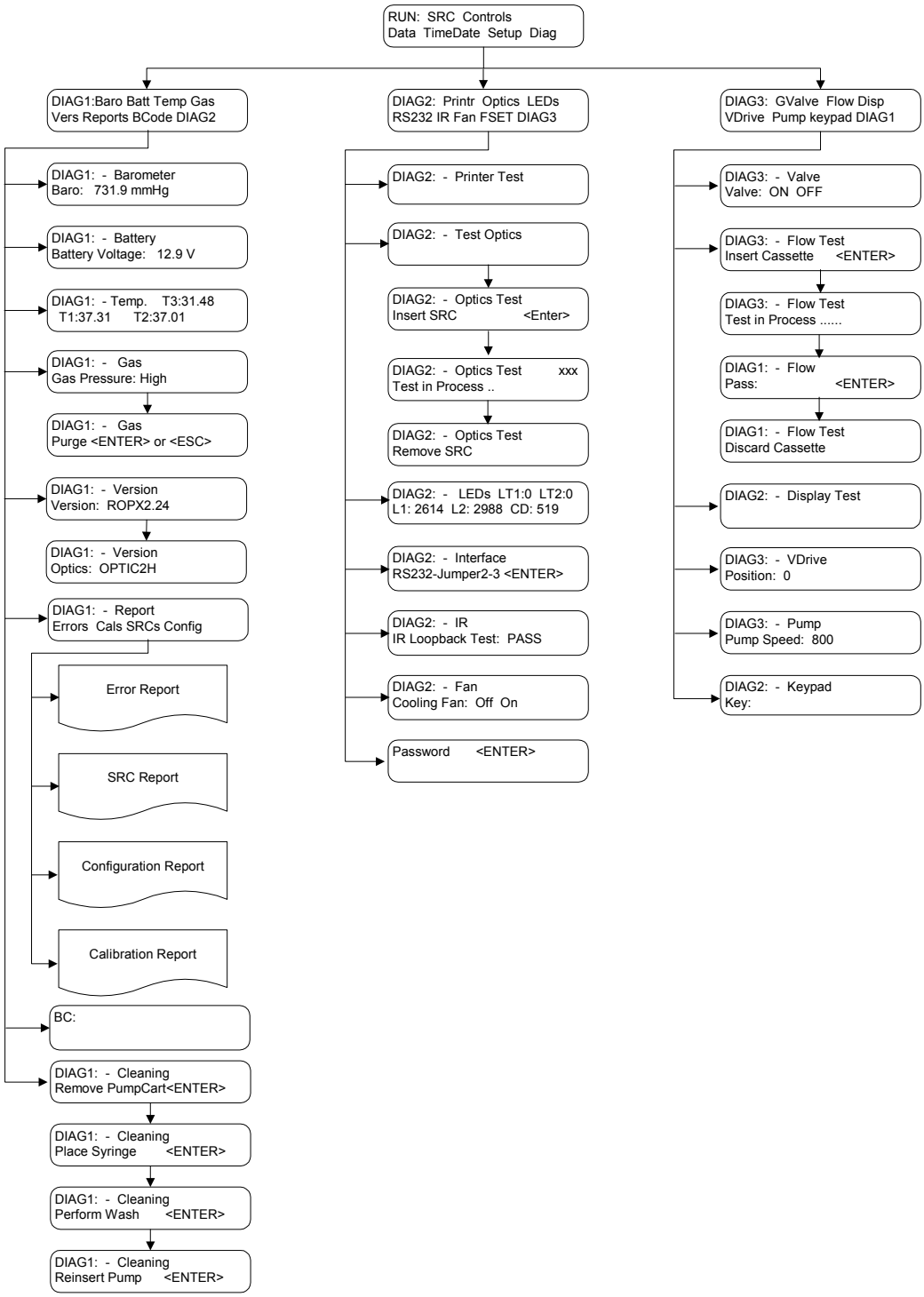


Fig. 2-16: Diagnostic Menu

3 Test Programs and Diagnostics

Osmetech OPTI™ 1 System

The Osmetech OPTI™ 1 is equipped with diagnostic routines designed to assist the user in testing the operation of the each system component. These tests can be selected in the **Diagnostics Menu.** An overview of the diagnostic tests available is located in Section 2. This section describes each diagnostic test and the expected result.

Diagnostic 1

Barometer

The BARO test displays the system barometric pressure in a real-time mode. This test can be used to verify the internal pressure transducer is measuring correctly. The barometric pressure should be compared to the laboratory reference standard and calibrated accordingly. The operator can adjust the barometric pressure by entering the correct value in the SETUP - BARO menu. To calibrate the internal barometer follow the adjustment procedure outlined in Chapter 7.

Battery

The Osmetech OPTI 1 may be powered by an internal battery pack or by an external battery charger, which is supplied with the analyzer. This test allows the user to determine the voltage of either the battery or external battery charger. When the charger is plugged in and connected to the analyzer, the display indicates the battery charger voltage. When the analyzer is powered from the internal battery, the displayed voltage is the battery voltage. When the internal battery powers the Osmetech OPTI 1, the voltage must be greater than 11.2 volts for correct operation. While the external battery charger is connected, the internal battery is being charged. The main board contains the required circuitry to monitor and control the battery charging system. An LED is visible through the rear cover indicating battery charge status. A solid ON light indicates the battery is charging, while a fast flashing light (4 times per second) indicates the battery is fully charged. The battery LED will be OFF when the analyzer is not connected to the external charger. A slowly blinking light (once per second) indicates a very cold, very hot or defective battery.

Temperature

The temperature diagnostic test displays three system-operating temperatures. T1 displays the SMC top plate temperature, T2 displays the SMC lower plate temperature and T3 displays the ambient temperature of the internal chassis and is used for the fan control. Circuitry on the main board, optics module, and SMC heater board provides temperature control for the analyzer. The following specifications are required for proper operation:

T1 = 37.00°C ±0.05°C
T2 = 37.15°C ±0.05°C
T3 = Internal analyzer temperature

Adjustment of the temperature circuitry is described in Chapter 4, Adjustments.

Gas Pressure

The newly installed calibration gas cylinder contains a gas pressure of 140-psi (9.7 bar) and is regulated and monitored by the gas module assembly. The gas pressure sensor portion of the module provides gas pressure status to the Osmetech OPTI 1 analyzer. If the gas bottle pressure falls below approx. 35 psi, the switch closes (low pressure). The pressure needs to be above approx. 50 psi for the switch to open (high pressure). This diagnostic test indicates HIGH PRESSURE or LOW PRESSURE depending on the remaining gas cylinder pressure. When this diagnostic test is completed, an additional screen is displayed to allow replacement of the gas bottle and a gas purge sequence to be initiated by the user.

Flow

Performing a flow test requires the use of a new cassette. The purpose of the flow test is to check proper operation of the pump, gas module and to detect leaks downstream from the pump.
At the end of the flow test, a pass/fail, as well as two flow numbers are displayed. If the flow numbers are 99.99, this part of the test failed and no number could be obtained.
Press Enter to start the test. First, the gas pressure is turned on (tubing upstream from pump is pressurized). With the pump stopped, the fluid light gates L1 and L2 check for the buffer to remain in the cassette. If the buffer is pushed out, the test fails and the pump cartridge needs to be replaced.
Now the pump starts pumping slowly, while L2 is looking for the trailing edge of the buffer. If the trailing edge is not detected within a certain time-out, the test fails. Check for leaks downstream from the pump. Replace the SMC gas seal and the pump cartridge receptacles.

Once L2 has detected the trailing edge, L1 is looking for the trailing edge of the buffer. L1 must detect the trailing edge between 1.2 seconds and 5.2 seconds. The actual time is indicated by the first number on the display at the end of the test. If the number is less than 1.2 seconds, replace the gas bottle and check the output pressure of the gas module (2.5 psi ± 0.5 psi).
Next, the system reverses the pump direction and measures the time of the buffer movement between LG1 and LG2. Since now the pump transports the buffer against the gas pressure, the time needs to be between 4.0 seconds and 8.0 seconds to pass the test. The second number displayed at the end of the flow test is the actual time. If the time is below 4.0 seconds, replace the gas bottle and check the output pressure of the gas module. If the time exceeds 8.0 seconds, replace the pump cartridge.

Diagnostic 2

Printer Test

The internal thermal printer can be tested using the printer test diagnostic. Selection of the printer test prints the following message:

```
  ! ” # $ % ’ ( ) * + , - . / 0 1 2 3 4 5 6 7 8
9 : ; < = > ? & ABCDEFGHIJKLMNOPQ
RSTUVWXYZ                    abcdefghij
klmnopqrstuvwxyz
```

Keypad Test

The keypad test when selected responds with the pressed key’s information displayed in the analyzer’s LCD display. Each key can be pressed successively until all keys have been tested. Press Esc twice to exit this diagnostic routine and to return to the diagnostic menu.

Display Test

The display test can be selected to test the LCD display module. As this test is selected, each of the 24 characters in both rows of the display will be illuminated to indicate the function of the entire display module. The test will repeat every several seconds until Esc is pressed to end the test.

Barcode Test

The barcode test is designed to test the function of either the internal barcode or the optional external barcode. To perform the barcode test press Enter to start the test. Swipe a valid barcode label and the analyzer will display the barcode information on the LCD display.

RS232 Test

The RS232 Serial Interface test is included to test the serial interface function. To perform the test, first select the RS232 test. Displayed instructions will request the user to jumper pin 2 & 3 of the 9-pin serial interface connector on the rear panel of the analyzer. When the jumper is in place, press Enter to start the test. Test results will be displayed indicating either PASS or FAIL.

Cover Test

The cover test is used to test the function of the SMC cover. When the cover is closed the display will indicate **Closed**. Open the SMC Cover and the display should indicate **Open**. To exit this test, press the Esc key and return to the diagnostic menu.

FSET

The FSET menu contains factory-set values stored in the EEPROM.

Diagnostic 3

Valve Test

The gas module incorporates two gas valves: an On/Off valve on the high-pressure side which enables/disables the gas flow, and a 3-way valve, which connects the pump to the vent or to the gas module. Both valves are wired in parallel, i.e. they are activated/deactivated simultaneously.
The valve test allows the user to test the gas valves. When the test is started, the analyzer displays the valve status. Pressing the right or left arrow key will turn OFF and ON the valve. Press Esc to exit the valve test.
This test can be used for checking adequate gas flow and the output pressure of the gas module (2.5 psi ± 0.5 psi). Remove the pump cartridge and turn the valve on. The gas will free-flow out the rear pump cartridge receptacle. Connect a piece of tubing and submerge it in water to check for adequate flow. Vigorous bubbles indicate adequate flow. If flow is inadequate, replace the gas module. To check the output pressure, connect a calibrated, digital pressure meter to the rear pump receptacle. If the pressure is outside the specified limits, replace the gas module. Note that output pressure is factory-set and cannot be adjusted.

Vdrive Test

The valve drive test is used to test and determine the position and movement of the valve drive. Select the Vdrive menu to begin the test. Position 0 will be displayed. Press the right arrow key to select valve position 1 - 12 and press Enter. The valve drive will move to the desired position. To test the home position, select position 0 and press Enter. When the valve drive has reached home position, insert a new cassette. The cassette should fit over the valve drive pins without any resistance. The home position can be adjusted using the Fset menu. Increasing the number will adjust the home position counter-clockwise, decreasing the number will adjust it clockwise.

Peristaltic Pump Test

The pump test is used to test the function of the peristaltic pump. When the pump test is selected, the Osmetech OPTI 1 will perform an automatic test of the peristaltic pump including clockwise and counter-clockwise rotation and a cycling of each pump speed used in normal operation. Once the test routine is started, correct pump operation can be observed by opening the printer access cover.
Note that the pump speed is computer-controlled and adjustment is therefore not necessary.

LED Test

The LED test displays the operating voltage of the internal LED's and allows for verification of operation and performance. The LED test will display the following LED's:

LT1	Cassette seat detect front (SMC Top Cover)
LT2	Cassette seat detect rear (SMC Top Cover)
L1	Front fluid detect LED
L2	Rear fluid detect LED
CD	Cassette detect LED

Memory Test

The **Memory Test** can be selected and the analyzer performs a check of the system memory. The analyzer displays **MEMORY OK** when the system successfully verifies the memory.

Software Version

Selecting the **Software Version** menu displays the currently installed software revision level. Pressing the right arrow key displays the software version for the optics module.

Reports

With the **Reports** menu, the user can select one of four reports to be printed.
The **Error Report** saves the last 50 system errors and can be printed. When the number of system errors exceeds 50 the oldest error is deleted and replaced by the most recent error.
A **Calibration Report** can also be printed which provides a calibration data summary of the stored patient and QC measurements.
The third report is an **SRC Report**, which provides a summary of all stored SRC results.
The **Configuration Report** prints out all user selectable settings. A printout of this report is particularly helpful prior to erasing memory (e.g. software update).

Error Report:

```
        Osmetech OPTI 1
        ERROR REPORT
       30-AUG-03   14:00
S/N: 1000

6-JUL- 03    08:45
ERROR - Cassette Misseat 2
```

Date/Time of error occurrence
Type of error

SRC Report:

```
        Osmetech OPTI 1
       SRC Diagnostic Report
        30-AUG-03   14:02
S/N: 1000
30Aug03 09:09 SRCID:742104
mV:     90.4     95.9     74.0
%DR:   0.06     0.09     0.06
%SEE:0.01      0.02     0.01
```

Date/Time of start of SRC run
Intensity/1000 must be > 7mV
Drift must be < 0.3% for all parameters
Noise must be < 0.2% for all parameters

Calibration Report:

```
        Osmetech OPTI 1
        Calibration Report
       30-AUG-03   14:00
S/N: 1000

30-AUG-03 11:18 LOT: 63407
          mV    Drift   T    W
pH        223.0   -2.4  33   102
PCO2      301.3   -0.4  33   103
PO2       625.9   -2.8  33   112
```

Date/Time of start of measurement
Intensity/1000 must be > 7mV
Drift during gas calibration, no limits apply
T: time needed for calibration in sec.
T must be less than 75 seconds
W: ratio between warm QC and gas cal.
pH and CO_2 must be with 5 units of each other
O_2 needs to be >93 and < 130
If T is out of limits: Bad Calibration Error
If W is out of limits: Bad Cassette Error

Configuration Report:

Osmetech OPTI 1 Configuration Report 30-AUG-03 14:02 S/N: 1000	This report prints the current programmed instrument configuration. This should be printed before changing instrument software.
Version: AOPX1.50	Current Software Version
Baro. Factor : 0.648	Barometric Pressure Sensor factor
Patient Info - Pat. ID : ON / Opt. Op. ID : ON / Opt. Temp. : ON tHb : ON Sex : ON Age : ON FIO_2 : ON Hb Type : ON P50 : ON RQ : ON Def. tHb : 15.0 g/dL Def. FIO_2 : 0.21 Def. RQ : 0.84 Def. P50 : 26.7 mmHg	Patient Information parameters programming
Reference Limits -	
Controls Info -	
Printouts -	
Calculated Parameters -	
Security -	
Miscellaneous -	
Correlation Factors -	
Communications -	
Language : English	
Battery Saver -	

Osmetech OPTI™ CCA System

The Osmetech OPTI™ CCA is equipped with diagnostic routines designed to assist the user in testing the operation of the each system component. These tests can be selected in the **Diagnostics Menu.** An overview of the diagnostic tests available is located in Section 2. This section describes each diagnostic test and the expected result.

Diagnostic 1

Barometer

The BARO test displays the system barometric pressure in a real-time mode. This test can be used to verify the internal pressure transducer is measuring correctly. The barometric pressure should be compared to the laboratory reference standard and calibrated accordingly. The operator can adjust the barometric pressure by entering the correct value in the SETUP – BARO menu. To calibrate the internal barometer follow the adjustment procedure outlined in Chapter 7.

Battery

The Osmetech OPTI CCA may be powered by an internal battery pack or by an external battery charger that is supplied with the analyzer. This test allows the user to determine the voltage of either the battery or external battery charger. When the charger is plugged in and connected to the analyzer, the display indicates the battery charger voltage. When the analyzer is powered from the internal battery, the displayed voltage is the battery voltage. When the internal battery powers the Osmetech OPTI CCA, the voltage must be greater than 11.2 volts for correct operation. While the external battery charger is connected, the internal battery is being charged. The main board contains the required circuitry to monitor and control the battery charging system. An LED is visible through the rear cover indicating battery charge status. A solid ON light indicates the battery is charging, while a fast flashing light (4 times per second) indicates the battery is fully charged. The battery LED will be OFF when the analyzer is not connected to the external charger. A slowly blinking light (once per second) indicates a very cold, very hot or defective battery.

Temperature

The temperature diagnostic test displays three system-operating temperatures. T1 displays the SMC top plate temperature, T2 displays the SMC lower plate temperature and T3 displays the ambient temperature of the internal chassis and is used for the fan control. Circuitry on the main board, optics module, and SMC heater board provides temperature control for the analyzer. The following specifications are required for proper operation:

T1 = 37.00°C ±0.05°C
T2 = 37.15°C ±0.05°C
T3 = Internal analyzer temperature

Adjustment of the temperature circuitry is described in Chapter 4, Adjustments.

Gas Pressure

The newly installed calibration gas cylinder contains a gas pressure of 140 psi (9.7 bar) and is regulated and monitored by the gas module assembly. The gas pressure sensor portion of the module provides gas pressure status to the Osmetech OPTI CCA analyzer. If the gas bottle pressure falls below approx. 35 psi, the switch closes (low pressure). The pressure needs to be above approx. 50 psi for the switch to open (high pressure). This diagnostic test indicates HIGH PRESSURE or LOW PRESSURE depending on the remaining gas cylinder pressure. Osmetech OPTI CCA serial numbers 4000 and up use a pressure transducer to measure the pressure in the gas bottle. In these analyzers, the diagnostic test indicates HIGH PRESSURE or LOW PRESSURE and displays remaining gas percent. When this diagnostic test is completed, an additional screen is displayed to allow replacement of the gas bottle and a gas purge sequence to be initiated by the user.

Version

Selecting the **Version** menu displays the currently installed software revision level. Pressing the right arrow key displays the software version for the optics module.

Reports

With the **Reports** menu, the user can select one of four reports to be printed. The **Error Report** saves the last 50 system errors and can be printed. When the number of system errors exceeds 50 the oldest error is deleted and replaced by the most recent error. A **Calibration Report** can also be printed which provides a calibration data summary of the stored patient and QC measurements. The third report is an **SRC Report**, which provides a summary of all stored SRC results. The **Configuration Report** prints out all user selectable settings. A printout of this report is particularly helpful prior to erasing memory (e.g. software update).

Error Report:

```
      Osmetech OPTI CCA
        ERROR REPORT
       30-AUG-03   14:00
S/N: 1000

6-JUL- 03    08:45
ERROR - Cassette Misseat 2
```

Date/Time of error occurrence
Type of error

SRC Report:

```
      Osmetech OPTI CCA
      SRC Diagnostic Report
       30-AUG-03   14:00
S/N: 1000
30Aug03 09:09 SRCID:742104
mV:     90.4    95.9    74.0
%DR:    0.06    0.09    0.06
%SEE:   0.01    0.02    0.01
```

Date/Time of start of SRC run
Intensity/1000 must be > 7mV
Drift must be < 0.3% for all parameters
Noise must be < 0.2% for all parameters

Calibration Report:

```
      Osmetech OPTI CCA
        Calibration Report
       30-AUG-03   14:00
S/N: 1000
Version: x.xx

30-AUG-03 11:18 LOT: 63407
          mV    Drift   T    W
pH      223.0   -2.4    33   102
PCO2    301.3   -0.4    33   103
PO2     625.9   -2.8    33   112
Na+     180.1    0.0    33   105
K+      452.4    7.2    33   93
Glu     491.3   -0.9    9    108
```

Date/Time of start of measurement
Intensity/1000 must be > 7mV
Drift during gas calibration, no limits apply
T: time needed for calibration in sec.
T must be less than 75 seconds

W: ratio between warm QC and gas cal.
pH and CO_2 must be with 5 units of each other
O_2 needs to be >93 and < 130
If T is out of limits: Bad Calibration Error
If W is out of limits: Bad Cassette Error

Configuration Report:

```
-------------------------

    Osmetech OPTI CCA
   Configuration Report
     DD-MMM-YY  HH:MM
S/N: XXXXX
Version: ABCX.XX

Baro. Factor : 0.000
Patient Info -
  Pat.ID     : ON / Opt.
  Oper.ID    : ON / Opt.
  AccNum.    : OFF / Opt.
  Temp.      : ON
  Sex        : ON
  Hb Type    : ON
  Sample Type: ON
  tHb        : ON
  MCHC       : ON
  O2 Mode    : OFF
  FIO2       : ON
  RQ         : ON
  P50        : ON
  Vent Mode  : ON
  TVol       : ON
  MVol       : ON
  PIP        : ON
  Pplat      : ON
  PS         : ON
  PEEP       : ON
  CPAP       : ON
  Rate       : ON
  Liter Flow : ON
  I/E Ratio  : ON
  BiLevel    : ON
  User Field : ON
  User Field2: ON
  User Field3: ON
  Def. tHb   :  15.0 g/dL
  Def. MCHC  :  33.3%
  Def. FIO2  : 0.21
  Def. RQ    : 0.84
  Def. P50   : 26.7 mmHg
Reference Limits -
  pH  7.200-7.600
  PCO2 30.0- 50.0 mmHg
  PO2  70.0-700.0 mmHg
  Na+ 135.0-145.0 mmol/L
  K+   3.50- 5.10 mmol/L
  Cl-  95.0-115.0 mmol/L
  Ca++ 1.12- 1.32 mmol/L
  Glu  60.0-120.0 mg/dL
  tHb  12.0- 17.0 g/dL
  SO2  90.0-100.0 %
```

```
Controls Info -
  Lev. 1 LimMin  LimMax
   pH   7.120-7.220
   PCO2  64.0-78.0 mmHg
   PO2   57.0-81.0 mmHg
   Na+  118.0-128.0 mmol/L
   K+    2.20- 3.20 mmol/L
   Cl-   50.0-160.0 mmol/L
   Ca++  0.20- 3.00 mmol/L
   Glu   30.0- 400.0 mg/dL
   tHb   17.9- 21.9 g/dL
   SO2   76.0-82.0 %
  QCLot: 9169 Exp: Jan03
  Lev. 2 LimMin  LimMax
   pH   7.380-7.460
   PCO2  40.0-48.0 mmHg
   PO2   88.0-112.0 mmHg
   Na+  140.0-150.0 mmol/L
   K+    4.00- 4.80 mmol/L
   Cl-   50.0-160.0 mmol/L
   Ca++  0.20- 3.00 mmol/L
   Glu   30.0- 400.0 mg/dL
   tHb   12.8- 15.8 g/dL
   SO2   86.0- 92.0 %
  QCLot: 9269 Exp: Jan03
  Lev. 3 LimMin  LimMax
   pH   7.550-7.650
   PCO2  18.0-26.0  mmHg
   PO2  132.0-156.0 mmHg
   Na+  156.0-166.0 mmol/L
   K+    4.80- 6.00 mmol/L
   Cl-   50.0-160.0 mmol/L
   Ca++  0.20- 3.00 mmol/L
   Glu   30.0- 400.0 mg/dL
   tHb    8.1- 11.1   g/dL
   SO2   93.0- 99.0  %
QCLot: 9369 Exp: Jan03
Units -
Units : Conventional
Temp  : Celcius
Time  : 24-hour
tHb   : g/dL
Resolution : High
Correlation Factors -
Normal Cassettes
             Slope  Offset
    pH       1.000  0.000
    PCO2       1.0    0.0
    PO2        1.0    0.0
    Na+        1.0    0.0
    K+        1.00   0.00
    Cl-        1.0    0.0
    Ca++      1.00   0.00
```

```
    Glu        1.0    0.0
    tHb        1.0    0.0
    SO2        1.0    0.0
Communications -
 Baud   : 9600
 Format  : RS232/ASTM/Full
Language: English
Battery Saver -
    AutoOff   : Always On
    Display   : Always On
FSET Values -
Version: ABCX.XX
IDAC1: 1464
IDAC2: 2024
IDAC3: 708
S/N: XXXXX
 pH False: 272
Low Limit: 278
Up Limit:  1985
Low offset: 500.000
Up factor:   0.800
Home offset: 240
PHR Correction: 160
PCR Correction: 75
K1:   3.5711  F1:   0.9717
K2:   3.2248  F2:   1.0010
K3:   0.8407  F3:   0.9825
K4:  -9.2500  F4:   0.0000
K5:  17.5040  F5:   0.0000
K6:   5.0090  F6:   7.9000
K7:  12.3660  F7;  44.7000
K8: 121.3850  F8:  11.4000
K9:   0.1321  F9:  41.4000
K10:  0.1428  F10: 15.8000
K11:  0.0040  F11:  2.0000
K12:  1.2586  F12: 48.5000
```

Barcode

The barcode test is designed to test the function of either the internal barcode or the optional external barcode. To perform the barcode test press Enter to start the test. Swipe a valid barcode label and the analyzer will display the barcode information on the LCD display.

Diagnostic 2

Printer Test

The internal thermal printer can be tested using the printer test diagnostic. Selection of the printer test prints the following message:

```
  ! ” # $ % ’ ( ) * + , - . / 0 1 2 3 4 5 6 7 8
9 : ; < = > ? & ABCDEFGHIJKLMNOPQ
RSTUVWXYZ                    abcdefghij
klmnopqrstuvwxyz
```

LED Test

The LED test displays the operating voltage of the internal LED’s and allows for verification of operation and performance. The LED 1 test will display the following LED’s:

LT1	Cassette seat detect front (SMC Top Cover)
L1	Front fluid detect LED
L2	Rear fluid detect LED
L3	Rear fluid detect LED

Press ENTER to view the second portion of the LED test. The LED 2 test will display the following LED’s:

Cover:	Open or Closed SMC Cover
CD	Cassette detect LED

Interface Test

The RS232 Serial Interface test is included to test the serial interface function. To perform the test first select the RS232 test. Displayed instructions will request the user to jumper pin 2 & 3 of the 9-pin serial interface connector on the rear panel of the analyzer. When the jumper is in place, press Enter to start the test. Test results will be displayed indicating either PASS or FAIL.

IR Test

The IR Loopback test is included to test the IR interface function. To perform the test first select the IR test. Test results will be displayed indicating either PASS or FAIL.

Fan Test

The FAN test allows the cooling fan to be turned ON and OFF using the analyzer keypad. Turn the FAN ON and check for proper airflow at the fan vents on the rear of the analyzer.

Note: The fan may only run for a short time. The software background task is still active in this menu, turning the fan off if the internal temperature is low.

Fset

The Fset menu contains factory-set values stored in the EEPROM.

Diagnostic 3

Valve Test

The gas module incorporates two gas valves: an On/Off valve on the high-pressure side which enables/disables the gas flow, and a 3-way valve that connects the pump to the vent or to the gas module. Both valves are wired in parallel and they are activated/ deactivated simultaneously.
The valve test allows the user to test the gas valves. When the test is started, the analyzer displays the valve status. Pressing the right or left arrow key will turn OFF and ON the valve. Press Esc to exit the valve test.
This test can be used for checking adequate gas flow and the output pressure of the gas module (2.5 psi ± 0.5 psi). Remove the pump cartridge and turn the valve on. The gas will free-flow out the rear pump cartridge receptacle. Connect a piece of tubing and submerge it in water to check for adequate flow. Vigorous bubbles indicate adequate flow. If flow is inadequate, replace the gas module.
To check the output pressure, connect a calibrated, digital pressure meter to the rear pump receptacle. If the pressure is outside the specified limits, replace the gas module. Note that output pressure is factory-set and cannot be adjusted.

Flow Test

Performing a flow test requires the use of a new cassette. The purpose of the flow test is to check proper operation of the pump, gas module and to detect leaks downstream from the pump.
At the end of the flow test, a pass/fail as well as two flow numbers are displayed. If the flow numbers are 99.99, this part of the test failed and no number could be obtained.
Press Enter to start the test. First, the gas pressure is turned on (tubing upstream from pump is pressurized). With the pump stopped, the fluid light gates L1 and L2 check for the buffer to remain in the cassette. If the buffer is pushed out, the test fails and the pump cartridge needs to be replaced.
Now the pump starts pumping slowly, while L2 is looking for the trailing edge of the buffer. If the trailing edge is not detected within a certain time-out, the test fails. Check for leaks downstream from the pump. Replace the SMC gas seal and the pump cartridge receptacles.
Once L2 has detected the trailing edge, L1 is looking for the trailing edge of the buffer. L1 must detect the trailing edge between 2.3 seconds and 4.5 seconds. The actual time is indicated by the first number on the display at the end of the test. If the number is less than 2.3 seconds, replace the pump cartridge.

Next, the system reverses the pump direction and measures the time of the buffer movement between LG1 and LG2. Since now the pump runs slower, the time needs to be between 3.8 seconds and 7.8 seconds to pass the test. The second number displayed at the end of the flow test is the actual time. If the time is out of range, replace the pump cartridge and check for leaks.

Display Test

The display test can be selected to test the LCD display module. As this test is selected, each of the 24 characters in both rows of the display will be illuminated to indicate the function of the entire display module. The test will repeat every several seconds until Esc is pressed to end the test.

VDrive Test

The valve drive test is used to test and determine the position and movement of the valve drive. Select the VDrive menu to begin the test. Position 0 will be displayed. Press the right arrow key to select valve position 1 - 12 and press Enter. The valve drive will move to the desired position. To test the home position, select position 0 and press Enter. When the valve drive has reached home position, insert a new cassette. The cassette should fit over the valve drive pins without any resistance. The home position can be adjusted using the Fset menu. Increasing the number will adjust the home position counter-clockwise, decreasing the number will adjust it clockwise.

Peristaltic Pump Test

The pump test is used to test the function of the peristaltic pump. When the pump test is selected, the Osmetech OPTI CCA will perform an automatic test of the peristaltic pump including clockwise and counter-clockwise rotation and a cycling of each pump speed used in normal operation. Once the test routine is started, correct pump operation can be observed by opening the printer access cover.
Note that the pump speed is computer-controlled and adjustment is therefore not necessary.

Keypad Test

The keypad test when selected responds with the pressed key's information displayed in the analyzer's LCD display. Each key can be pressed successively until all keys have been tested. Press Esc twice to exit this diagnostic routine and to return to the diagnostic menu.

4 Adjustments

Osmetech OPTI™ 1 System

The Osmetech OPTI™ 1 is designed to require only minimal adjustments by field service personnel. The main board contains 6 electrical adjustments; however, field service personnel may make only three adjustments.
Three potentiometers (R40, R100, and R136) are sealed and are factory adjustments only. These factory-only adjustments require special test fixtures and can only be performed at the factory. Field personnel may make the following adjustments:

Barometric Pressure (R35)

Sample Measurement Chamber Temperature (R97 and R95)

Caution: For all adjustments, first turn the analyzer power off, disconnect analyzer from primary power and remove installed battery to avoid electrical damage.

Open the analyzer lower housing by removing seven screws on the bottom of the analyzer. Set the analyzer upper housing on its side to access the keypad. Turn the analyzer power on. After completion of the adjustments, turn off the analyzer power before reassembly of the analyzer. Once reassembly is completed, turn the analyzer power on to resume normal operation.

Barometric Pressure

The operator through keyboard entry in the Setup mode may adjust barometric pressure. The displayed pressure may be adjusted ± 50 mmHg through keyboard entry. Use the following procedure if barometric pressure requires adjustment beyond the span of the keyboard entry.

Using the analyzer keypad, select the Diagnostics Menu and then the barometer test to enable the barometric pressure. Locate R35 and adjust for the correct barometric pressure on the analyzer display.

Sample Measurement Chamber Temperature

Note: Prior to performing temperature adjustment turn on the analyzer power and allow a 10-minute warm-up to ensure temperature stability.

Using the analyzer keypad, select the Diagnostics Menu and then the temperature test to enable the display of analyzer temperature. For temperature T1, locate R97 and adjust for a display of 37.00 ±. 0.03 °C. After adjustment of R97 allow 5 minutes for temperature to stabilize. Locate R95 and adjust for a display of 37.15 ±0.03 °C for temperature T2.

Note: Always adjust temperature T1 before adjusting T2 as temperature T2 depends on temperature T1. R95 adjusts the difference between T1 and T2 which must be 0.15 °C.

Osmetech OPTI™ CCA System

The Osmetech OPTI CCA is designed to require only minimal adjustments by field service personnel. The main board contains nine electrical adjustments; however, field service personnel may make only three adjustments. Six potentiometers are factory adjustments only:

R74	Barometer Slope
R129	Top Cover Temperature
R161	Optics Temperature
R215	Laser Intensity
R217	Laser Intensity
R277	LED Intensity (tHb/SO_2)

These factory-only adjustments require special test fixtures and can only be performed at the factory.

Field personnel may make the following adjustments:

Barometric Pressure (R67)

Sample Measurement Chamber Temperature
(R126 and R124)

Caution: For all adjustments, first turn the analyzer power off, disconnect analyzer from primary power and remove installed battery to avoid electrical damage.

Open the analyzer lower housing by removing seven screws on the bottom of the analyzer. Set the analyzer upper housing on its side to access the keypad. Turn the analyzer power on. After completion of the adjustments, turn off the analyzer power before reassembly of the analyzer. Once reassembly is completed, turn the analyzer power on to resume normal operation.

Barometric Pressure

The operator through keyboard entry in the Setup mode may adjust barometric pressure. The displayed pressure may be adjusted ± 50 mmHg through keyboard entry. Use the following procedure if barometric pressure requires adjustment beyond the span of the keyboard entry.

Using the analyzer keypad, select the Diagnostics Menu and then the barometer test to enable the barometric pressure. Locate R67 and adjust for the correct barometric pressure on the analyzer display.

Sample Measurement Chamber Temperature

Note: Prior to performing temperature adjustment turn on the analyzer power and allow a 10-minute warm-up to ensure temperature stability.

Using the analyzer keypad, select the Diagnostics Menu and then the temperature test to enable the display of analyzer temperature.
Locate R126 and adjust for a display of 37.00 ±. 0.03 °C for temperature T1.
After adjustment of R126 allow 5 minutes for temperature to stabilize.
Locate R124 and adjust for a display of 37.15 ±. 0.03 °C for temperature T2.

Note: Always adjust temperature T1 before adjusting T2 as temperature T2 depends on temperature T1. R124 adjusts the difference between T1 and T2 which must be 0.15 °C.

5 Troubleshooting

Osmetech OPTI™ System

The Osmetech OPTI™ 1 and Osmetech OPTI™ CCA analyzers are equipped with sensors and diagnostic software that control, monitor and detect analyzer system status. Operator messages indicating system status are displayed to provide the operator with useful information to determine the cause of detected system errors or malfunctions. System errors are also stored in memory and an error report can be printed that lists the last 50 status messages.

Displayed Alarms

There are four types of displayed system status messages:

SYSTEM STOP ALARMS

These alarms indicate system conditions that must be resolved before system operation can be continued.

SYSTEM ERROR ALARMS

These errors occur during sample analysis and are specific to the current sample being analyzed. Error alarms indicate the status of the current measurement or additional required operator entry.

SYSTEM WARNING MESSAGES

System warning messages notify the operator of conditions requiring operator intervention to complete the current measurement.

SYSTEM INFORMATION MESSAGES

These messages describe operator instructions or confirm completion of operator selections.

The following section describes each displayed message and the causes and conditions that generate this message. Further in the chapter probable causes and fault isolation are provided for each status message.

SYSTEM STOP MESSAGES

STOP - Temp Out of Range Please Wait Menu<ENTER>

When the sample measurement chamber bottom plate temperature is outside the range of 37.10°C to 37.20°C or the top plate is outside the range of 36.95°C to 37.05°C this error is displayed. Normal operation can only be resumed when the temperature is in range. To check the system temperature, access the **DIAG1 Temperature** menu to display system temperature. Temperature T1 indicates top plate temperature while T2 indicates bottom plate temperature. If this error condition remains, perform temperature adjustment procedure as described in Section 7, Adjustments.

STOP - Low Battery Recharge Now

During prolonged periods of use, the battery charge may become depleted and normal operation can no longer be continued. This message will be displayed when the battery voltage is less than 11.2 volts. System operation is halted until the error condition is resolved in order to prevent the possible memory corruption. Replace the battery pack with a fully charged spare or connect the battery charger to recharge the battery pack.

STOP - Low Battery Recharge and Cycle Power

If the battery voltage drops below 10.5 V, the unit will lock up to prevent memory corruption. To resume operation, connect the instrument to the power supply and cycle the power.

STOP - Low Gas Replace Now <ESC>

An internal gas cylinder is used to provide a calibration gas source that is used when calibrating each sample cassette. When the gas pressure sensed by the internal gas manifold assembly detects pressure below 35 psi, too low to perform a successful calibration, this error is displayed. Replace the gas cylinder with a full cylinder to continue normal operation. Access **DIAG1 Gas** to display the current gas pressure status.

```
STOP - Need New SRC Data
Must Run SRCs     <ESC>
```

Standard Reference Cassettes (SRC's) are measured to verify the analyzer's measuring performance. In analyzer programming, the key operator may select QC Lockout for 1, 2 or 3 levels. Depending on the selection, 1, 2 or 3 levels of SRC's are required to be run daily. If no SRC records for the last 24 hour period exist in the database, this message is displayed. Performing SRC measurements of the levels required will remove this error message.

```
STOP -  System Error
Cycle Power for Reset
```

The STOP System Error is displayed when the operating software detects incorrect communication between the main microprocessor and the optics module microprocessor and halts routine operation. This indication may occur if the system software becomes corrupted. Generally, cycling power OFF and then ON can restart the system. The Osmetech OPTI will restart and complete the start-up initializing routine for normal operation.

```
STOP - New Cassette Lot
Must Run Controls  <ESC>
```

When "New Lot" or "Controls" is selected under QC-Lockout, the Osmetech OPTI will detect a difference in the cassette lot number from the previous cassette. When the difference is detected, the **Stop - New Cassette Lot** message is displayed. To continue the operator must verify the new lot of cassettes by measuring QC material.

```
STOP - Memory Error
Database Deleted   <ESC>
```

Vital analyzer parameters are stored in the system's EEPROM. Upon each power on, this EEPROM data is checked against its copy in RAM. If the values do not match due to memory corruption, this error is displayed. The analyzer will perform a complete reinitialization which includes deletion of the stored data. In addition, for diagnostic purposes, a report outlining the old values in RAM and the new initialized values can be printed if Enter is pressed.

SYSTEM ERROR MESSAGES

```
ERROR - Unstable Sensors
Discard Cassette   <ESC>
```

This error occurs during a sample measurement. In this condition the cassette successfully calibrated and detected correct aspiration of the sample. During a sample measurement, the Osmetech OPTI monitors each of the sensor's output for an endpoint. When two or more parameters continue to drift and do not reach endpoint this message is displayed.

```
ERROR-Cassette MisSeat 1
Reinsert  or      <ESC>
```

When the Osmetech OPTI detects that the SMC Cover has been closed, the SMC top light gates LT1 and LT2 are checked to ensure proper seating of the cassette. If a cassette has been misseated, the spring loaded top plate is not in its correct position and causes either of the SMC top light gates to sense this misseat condition. Open the SMC cover and reposition the cassette. If error persists, insert a new

```
ERROR-Cassette MisSeat 2
Reinsert  or     <ESC>
```

Once a cassette has been inserted into the SMC and the cover is closed, the front and rear light gates LG1 and LG2 detect buffer is present in the cassette. Normally the buffer is removed during the calibration process. When this message is displayed, the Osmetech OPTI assumes the cassette is seated improperly or the cassette is not sealed firmly to the SMC port. Open the SMC cover and reposition the cassette.

```
ERROR-Cassette MisSeat 2
Discard Cassette   <ESC>
```

If reinserting the cassette does not eliminate the Cassette Misseat Error, this message will be displayed.

```
ERROR  -  Bad Cassette
Discard Cassette   <ESC>
```

During cassette calibration, each sensor is checked for an endpoint. If all sensors reach endpoint, calculations are performed for each sensor comparing calibration information to initial optics data. This message is displayed if two or more of the sensor calculations are outside the limits.

```
ERROR - Bad Calibration
Discard Cassette   <ESC>
```

If two or more sensors did not reach a stable endpoint, the calibration is considered "failed" and this message is displayed.

```
ERROR  -  Cal Expired
Discard Cassette   <ESC>
```

Following insertion of a cassette, a one-point cassette calibration will occur. The cassette will remain calibrated for a 10-minute period. If no measurement occurs within 10 minutes, the cassette will be recalibrated. This process will continue for up to 30 minutes. If no sample has been aspirated during this thirty-minute interval, the cassette must be discarded. For the Osmetech OPTI CCA, the calibration expires in 10 minutes.

```
ERROR  -  Dirty Optics
Clean Cass./Optics <ESC>
```

After the cassette has been repositioned following an initial Misseat 2 Error, the sample light gates LG1 and LG2/(LG3) monitor the transition in the cassette from buffer to air. When the cassette buffer is removed, the light gates can not detect this buffer-to-air transition. The Osmetech OPTI assumes that the optics are dirty when no buffer transition is detected.

```
ERROR - Bad Sensors
Discard Cassette   <ESC>
```

After insertion of a new cassette, an optics test is performed. Each sensor must provide a reading of greater than 10,000 counts for an adequate sensor output. If any sensor fails to meet these criteria, no sample measurement can be performed. A manual optics test can be performed in System Diagnostics to confirm the cassette performance.

```
ERROR - Invalid Barcode
Continue        <ENTER>
```

During sample analysis the barcode is read. If the analyzer is unable to determine the barcode information or the system software does not support the barcode format this message will be displayed. The barcode information is checked to determine if the barcode is a cassette, compares the checksum, and compares calibration parameters to expected ranges. A barcode test can be performed by accessing **DIAG Barcode** and swiping a valid barcode. The barcode data will be displayed. The Osmetech OPTI currently supports the following barcode formats: Codabar, Code39, Interleaved 2 of 5, UPC, EAN.

```
ERROR - Invalid Barcode
Check TimeDate   <ENTER>
```

If the expiration date does not match the current date/time setting, this message is displayed.

```
ERROR - No Pat. ID Entry
Edit Data<ENTER>or<ESC>
```

During analyzer setup and programming a selection can be made to require entry of patient ID for each sample analyzed. The analyzer will not report sample results until a patient ID is entered. Enter a patient ID to obtain a printed sample report.

ERROR - No Op. ID Entry Edit Data<ENTER>or<ESC>

During analyzer setup and programming a selection can be made to require entry of operator ID for each sample analyzed. The analyzer will not report sample results until an operator ID is entered. Enter an operator ID to obtain a printed sample report.

ERROR - Expired Barcode Check Time Date <ENTER>

Each measurement cassette and Standard Reference Cassette (SRC) is provided with a barcode label that must be read prior to insertion of the cassette into the analyzer.
The barcode contains measurement information, lot number and expiration date. This message is displayed when the expiration date indicated in the barcode information has been exceeded. To resolve this error, first check analyzer time and date settings. If the settings are correct remove the SRC or measurement cassette and discard the expired cassette. Select an in-date cassette to perform the measurement.

ERROR - Possible Clot Discard Cassette <ESC>

During sample aspiration the SMC light gates LG1 and LG2 (LG3 for Osmetech OPTI CCA) are used to detect proper sample aspiration. When LG1 detects sample has been aspirated at the beginning of the sensor path and LG2/LG3 fails to detect sample aspiration at the end of the sensor path, the warning of a possible clot is displayed.

ERROR - Invalid Sample Discard Cassette <ENTER>

In the OPTI-trol mode, a blood sample must be measured after the OPTI-trol measurement.

ERROR - Gas Expired <ESC>

Each gas bottle is provided with a barcode label, which must be read prior to insertion of the gas bottle.
This message is displayed when the expiration date on the barcode has been exceeded.
First check whether the analyzer time/date setting is correct. Then replace gas bottle with an in-date bottle (check expiration date on new bottle).
Note: The in-use expiration date may occur prior to the expiration date printed on the gas bottle label.

ERROR - No ID Entry Edit Data<ENTER>or<ESC>

During analyzer setup, a selection can be made to require entry of patient ID and operator ID for each sample analyzed. If this function is selected, the analyzer will not report sample results, until a patient and/or operator ID is entered.

SYSTEM WARNING MESSAGES

```
WARNING - Low Gas
1 Test Remaining   <ESC>
```

The gas manifold assembly continually monitors gas pressure when the Osmetech OPTI is in use. When the pressure is less than 25 psi, the **Low Gas** warning is displayed to indicate that the remaining gas pressure can perform only one additional sample measurement.

```
WARNING – Gas Expires
Soon!   Continue <ENTER>
```

The Gas expiration date is monitored based on the barcode that was swiped into the Osmetech OPTI's memory at the time of the last gas canister change. This message alerts the operator that there is 2 weeks usage remaining for the gas tank. The operator can continue normal operation by pressing Enter.

```
WARNING
No Sample Detected
```

The Osmetech OPTI requires a minimum of 80µL (Osmetech OPTI CCA 120µL) of blood or a minimum of 110µL (Osmetech OPTI CCA 120µL) of clear fluid such as QC material to perform a measurement. Sample light gates LG1 and LG2/(LG3) in the sample measurement chamber (SMC) detect the leading and trailing edge of the sample in order to determine if the minimum amount of sample is aspirated. When LG1 does not detect sample aspiration, this message is displayed.

```
WARNING  -  Low Battery
1 Test Remaining   <ESC>
```

During battery operation of the analyzer, the Osmetech OPTI continually monitors the battery voltage. When the operating voltage of the battery is less than 11.8 volts and greater than 11.2 volts a battery warning is displayed. This informs the operator to plug in the battery charger or install a fully charged battery prior to an interruption of system operation.

```
WARNING-Bad Sensor - pH
Continue<ENTER>or<ESC>
```

```
WARNING-Bad Sensor- CO2
Continue<ENTER>or<ESC>
```

```
WARNING-Bad Sensor - O2
Continue<ENTER>or<ESC>
```

```
WARNING-Bad Sensor- Na
Continue<ENTER>or<ESC>
```

```
WARNING-Bad Sensor - K
Continue<ENTER>or<ESC>
```

```
WARNING-Bad Sensor – Cl-
Continue<ENTER>or<ESC>
```

```
WARNING-Bad Sensor– Ca++
Continue<ENTER>or<ESC>
```

```
WARNING-Bad Sensor- Glu
Continue<ENTER>or<ESC>
```

These warning messages indicate a single sensor has an output of less than 7,000 counts. The warning message may appear either during the calibration or sample measurement process. If this message occurs during sample measurement, check sample preparation. These warning messages are displayed and are specified for each measurement parameter. When this warning is displayed no sample measurement results will be reported for the parameter identified, however results will be reported for the other parameters.

```
WARNING -  Unstable pH
Check Cassette
```

```
WARNING - Unstable PCO2
Check Cassette
```

```
WARNING -  Unstable PO2
Check Cassette
```

```
WARNING - Unstable  Na
Check Cassette
```

```
WARNING -  Unstable  K
Check Cassette
```

```
WARNING- Unstable – Cl-
Continue<ENTER>or<ESC>
```

```
WARNING- Unstable – Ca++
Continue<ENTER>or<ESC>
```

```
WARNING - Unstable  Glu
Check Cassette
```

This warning may be displayed during a calibration or measurement sequence and indicates a single sensor failed to reach an acceptable endpoint. The warning is displayed and indicates the sensor that does not reach endpoint in the right column of the display. If this warning occurs during sample analysis, check the cassette for air bubbles in the cassette upon the completion of the measurement sequence. If the warning is displayed during calibration, the parameter having the warning will not provide results.

```
WARNING- Bubble Detected
Check Cassette   <ENTER>
```

This message is displayed when the Osmetech OPTI has detected an air bubble during sample aspiration. This message is displayed before the final results are displayed so the operator can be alerted to check the cassette for possible bubbles.
If an air bubble is sensed during sample aspiration, the aspiration routine is retried for up to 3 additional cycles. If all aspiration retries fail, the analyzer will display a **No Sample** Error. For a description of the aspiration cycle and bubble detect routine, refer to the **ERROR - No Sample** description.

```
WARNING - Check Pump
Continue <ENTER> or<ESC>
```

During a cassette calibration cycle, the peristaltic pump will pump calibration gas into the cassette. When the gas is being pumped into the cassette, the buffer in the cassette is pumped into the cassette reservoir. SMC light gates LG1 and LG2 are monitored during this time to detect the buffer evacuation in a precise time interval. If the light gates detect an improper evacuation of the buffer, the pump warning message is displayed.

```
WARNING  -  Check Pump
Please remove cassette
```

If pressing Esc twice to the above error message does not resolve the **Check Pump** condition, this message will be displayed.

```
WARNING - No PatID Entry
Continue         <ENTER>
```

```
WARNING - No Op ID Entry
Continue         <ENTER>
```

```
WARNING - No ID Entry
Continue         <ENTER>
```

During analyzer setup and programming a selection can be made to require entry of a patient and/or operator ID for each sample analyzed. The analyzer will not report sample results until a patient and/or operator ID is entered. Enter the required ID to continue sample measurement.

SYSTEM INFORMATION MESSAGES

No SRC Record (Level X)	When the operator has requested a printed report of the SRC measurement statistics and no records are stored in the SRC database this status message will be displayed. The displayed message also identifies the applicable SRC Level for which no SRC records exist.
SRC Database Deleted (Level X)	When the Osmetech OPTI analyzer detects a new SRC ID, the operator is prompted to delete all current SRC data (password protected). As the operator enters the correct password and replies Esc to delete the SRC data, the analyzer prints the SRC statistical report and confirms deletion of the SRC data with this displayed message.
Please Wait Printing Stopped	While the Osmetech OPTI internal thermal printer is printing a report, the operator may press Esc to abort printing. The analyzer will display this message until the current report is restarted or the operator presses Esc a second time to abort the print cycle.
Please Leave Cassette & Close the Cover	Following a sample measurement, the cassette reservoir is locked and the sample waste is sealed inside the cassette. This reservoir locking prevents the biohazardous waste from leaking and forms a sealed container for the sample waste. If the SMC Cover is opened prematurely in order to discard the cassette and the valve drive has not been turned to the locking position, this message is displayed. Close the cover and wait for the analyzer to prompt for cassette removal.
Terminate Operation: N Y	During an operating sequence of the Osmetech OPTI, the operator may select to abort the current operation. To do this, press Esc and then "0". The analyzer then displays this message and waits for a key response (Enter or Esc) before terminating the current operation.

```
Not Enough Records
(Level  X)
```

The Osmetech OPTI stores QC results and SRC results in an internal database. Cumulative statistics printed or displayed in the system software are calculated based on the stored data. A minimum of 2 data points is required in order to calculate statistical results. This message is displayed when too few records exist in the database to provide a result. Enter additional QC or SRC measurement data when this message is displayed.

```
Control Database Deleted
(Level  X)
```

When a new lot of QC material is to be run, the assay or package insert values must first be entered (under password control). As the operator enters a new lot number, the Osmetech OPTI will prompt the operator to print and then delete the old QC data. As the QC records are deleted, this message is displayed to confirm the deletion of the QC database has occurred.

```
Operation: Halted !
Please Close the Cover
```

If the sample measurement chamber (SMC) cover is opened during a critical time (during calibration, aspiration or measurements), this message will be displayed. Close the SMC cover to continue normal operation.

```
New SRC Lot !
```

During an SRC measurement, the SRC ID number is checked by the barcode information. If the Osmetech OPTI analyzer detects an ID number that differs from that of previous SRC measurements, the **New SRC** warning is displayed. The operator may select Enter to continue or Esc to exit the SRC measurement process.

```
Cassette Expired
<ESC>
```

If an operator swipes a cassette barcode and the expiration date of the cassette has been exceeded, this message will be displayed. Check the analyzer TIME and DATE for the correct entry. If the time and date are correct replace the cassette lot with an in date lot.

Troubleshooting

The Osmetech OPTI provides display messages indicating the status of the analyzer. The previous section describes the conditions in which error, warning or system information messages may occur. This section contains troubleshooting tables to define possible causes and instructions for remedial action. In addition, troubleshooting flowcharts are provided for the most common error occurrences.

Error Message	Possible Causes	Remedial Action
WARNING -Low Battery 1 Test Remaining <ESC>	Battery voltage >11.2 and < 11.8 volts.	Replace battery pack with a fully charged battery. Plug in battery charger, check Charge LED is ON. The charger will charge a depleted battery while connected to AC power in approximately 6 hours. If the battery will no longer accept a charge replace the battery with a new battery pack. Check the charge LED status; a solid ON indicates the battery is charging, a fast flashing ON LED (4 times/second) indicates battery is fully charged. If the charge LED is OFF this indicates the charger is not connected. Replace charger or replace the main board. A slow flash (1 flash per second) indicates the battery voltage is below 9.5 volts or the battery thermistor senses an excessively hot or cold battery. Replace the battery if this indication persists.
STOP - Low Battery Recharge Now	Battery voltage <11.2 volts and the analyzer will stop operating.	See above troubleshooting hints. When the battery voltage rises above 11.2 volts the analyzer will resume operation.

Error Message	Possible Causes	Remedial Action
STOP - Low Battery Recharge and Cycle Power	Battery voltage drops below 10.5 V.	Connect power supply and cycle power.
STOP - System Error Cycle Power for Reset	At power-up software is not initialized correctly.	Turn power OFF and ON to retry. Check interconnect cables for a secure connection. Perform system initialization. Replace SMC module. Replace main board.
STOP - Temp Out of Range Please Wait Menu <Enter>	SMC top plate temperature T1 must be 37.00°C ± 0.05 and bottom plate T2 must be 37.15°C ± 0.05.	Check fuse F2. Perform Temperature Diagnostic check to determine current temperature. Perform Temperature circuit adjustment. Install SW Version ≥ 1.10 Replace SMC module Replace main board. Replace heater board in SMC cover.
WARNING - Low Gas 1 Test Remaining	The gas cylinder is near empty and has only enough pressure to perform one additional measurement.	Replace gas cylinder with a full cylinder. Replace gas module assembly.
STOP - Low Gas Replace Now <ESC>	The pressure of the gas cylinder is empty. No measurements can be made.	See troubleshooting hints above.

Error Message	Possible Causes	Remedial Action
STOP - Memory Error Database Deleted <ESC>	RAM data has been changed, corrupted, or lost, or a new software version has been installed	Press ESC and all factory settings will be copied from EEPROM to RAM.
ERROR - Invalid Barcode Continue <ENTER>	During barcode swipe, the read barcode information is not in the correct format (i.e. SRC barcode is swiped for a normal measurement).	Check the correct menu is selected. Select a cassette barcode and swipe to determine barcode function. Perform barcode diagnostic test. Perform system initialization. Check barcode format is supported by the Osmetech OPTI. Clean barcode lens. Replace internal or external barcode assembly. Replace main board.
ERROR - Invalid Barcode Check Time/Date <ENTER>	The expiration date does not match the current date setting	Check correct Time/Date setting
STOP - Need New SRC Data Must run SRC's <ESC>	If QC lockout has been selected to require daily SRC measurement, SRC's must be run at least once per day.	Run required daily SRC measurements.
STOP - New Cassette Lot Must Run Controls <ESC>	New Lot has been selected in QC Lockout and a new lot of cassettes was detected. The new lot of cassettes must be verified with quality control material.	Select a cassette from the current lot and run measurement. Run QC material to verify the new lot of cassettes.

Error Message	Possible Causes	Remedial Action
ERROR - Cassette Misseat 1 Reinsert or <ESC>	Top cover light gates LT1 and LT2 detect a cassette not seated properly.	Open cover and reposition the cassette. Retry with new cassette. Perform LED test in system Diagnostics. Replace SMC cover.
ERROR - Cassette Misseat 2 Reinsert or <ESC>	During displacement of buffer, the rear light gate LG2 fails to detect a transition from buffer to air.	Open cover and reposition the cassette. Retry. Discard cassette and retry with a new cassette. Replace SMC seal. Perform flowtest. Check pump cartridge is seated correctly, replace if necessary. Check valve drive position. Check for adequate gas flow
ERROR - Cassette Misseat 2 Discard Cassette <ESC>	If above error occurs repeatedly, this message is displayed.	Discard cassette.
ERROR - Bad Sensors Discard Cassette <ESC>	During a cassette calibration, the optode sensors did not have sufficient signal output.	Check cassette foil pouch for tears or leaks. Make sure cassette pouch was opened within 10 minutes from start of measurement. Clean glass optics plate. Try a new cassette.

Error Message	Possible Causes	Remedial Action
ERROR - Bad Calibration Discard Cassette <ESC>	Two or more sensors failed to reach endpoint during calibration cycle.	Discard cassette and retry with a new cassette. Check for leaks in fluidic tubing. Check for proper seating of pump cartridge.
ERROR - Unstable Sensors Discard Cassette	Sample preparation or sample with high or extreme measurement characteristics.	Check cassette for air bubbles or voids over sensors. Thoroughly mix sample prior to measurement.
ERROR - Expired Barcode Check Time/Date <ENTER>	Cassette date code has expired.	Use cassette with an in-date expiration. Check for current date and time.
ERROR - Bad Cassette Discard Cassette <ESC>	Cassette optics characteristics failed during cassette check.	Check cassette foil pouch for leaks or tears. Make sure cassette pouch was opened within 10 minutes from start of measurement. Discard cassette.
ERROR - Cal Expired Discard Cassette <ESC>	After calibration of the cassette a sample must be run within 10 minutes. If no sample is entered, the analyzer will perform another calibration. This process will be repeated for up to 30 minutes, then the cassette must be discarded. Osmetech OPTI CCA calibrations expire after the first 10 minute period.	Run a sample measurement within 30 minutes after cassette insertion. Open a new cassette and retry.

Error Message	Possible Causes	Remedial Action
ERROR - Dirty Optics Clean Cass./Optics <ESC>	Sample light gates LG1 and LG 2 fail to calibrate. SMC Optics may have become dirty with blood residual.	Wipe residual from cassette prior to insertion. Clean glass optics plate. Discard cassette and try new cassette. Perform Diagnostic LED Test. Make sure green LED's in SMC cover light up. Replace SMC cover.
ERROR - Gas Expired <ESC>	Gas bottle barcode expired. In-use life expired. Instrument time/date setting incorrect.	Replace with new gas bottle. Set correct time/date.
ERROR - No Pat. ID Entry Edit Data <ENTER> or <ESC>	Patient ID is selected as a required entry for all measurements.	Press <ENTER> to continue and enter a Patient ID for the sample. Results will be displayed and will not be printed until an ID has been entered.
ERROR - No Op. ID Entry Edit Data <ENTER> or <ESC>	Operator ID is selected as a required entry for all measurements.	Press <ENTER> to continue and enter an Operator ID for the sample. Results will be displayed and will not be printed until an ID has been entered.
ERROR - No ID Entry Edit Data <ENTER> or <ESC>	Patient and operator ID was selected as a required entry for all measurements.	Press <ENTER> to continue and enter an operator and patient ID for sample results.
WARNING - Bubble Detected Check Cassette	LG 1 detected sample aspiration and detected air prior to sample reaching LG 2.	Check cassette for air bubbles or insufficient sample volume.

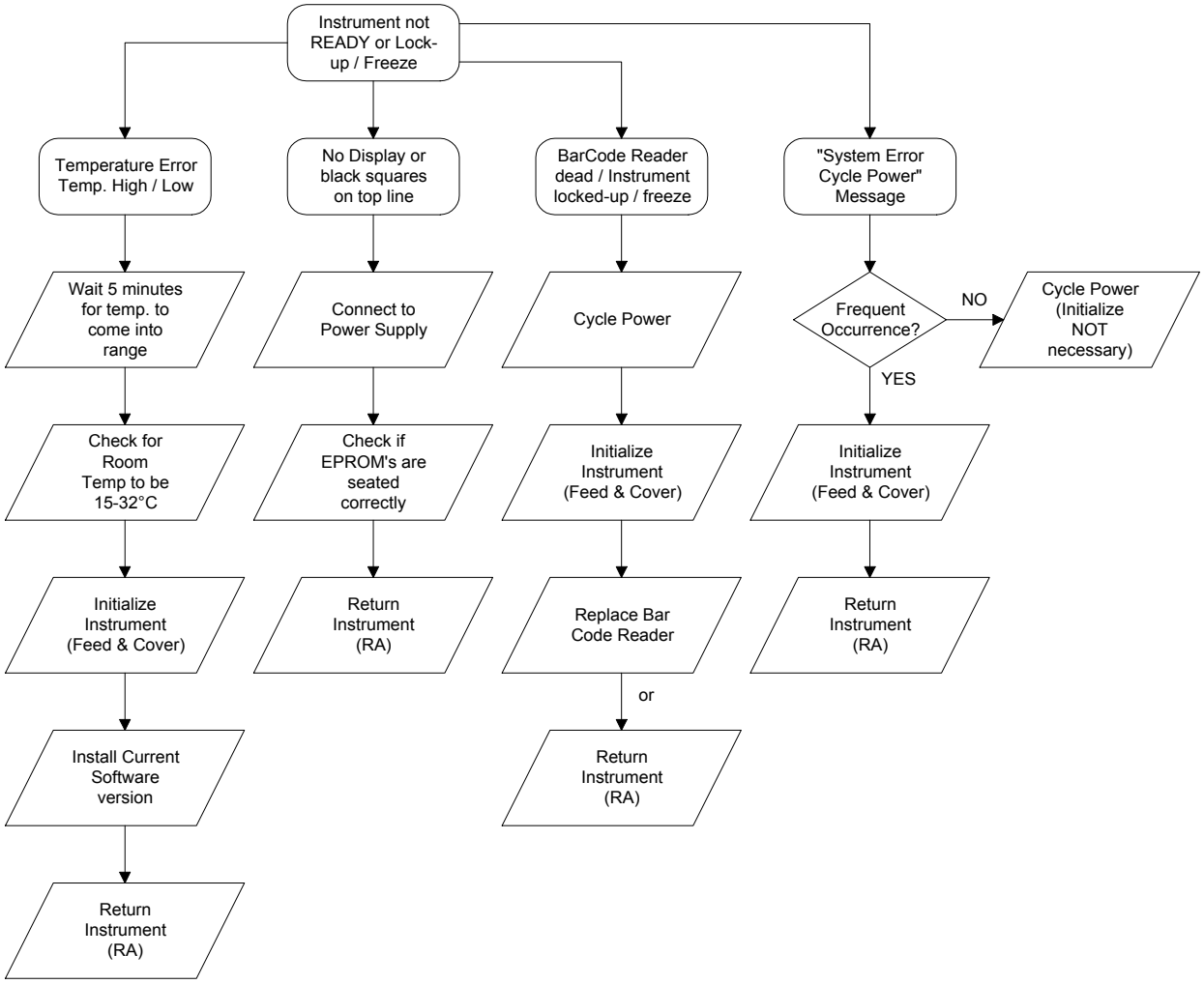
Error Message	Possible Causes	Remedial Action
ERROR Possible Clot Discard cassette <ESC>	LG 1 detected sample aspiration and analyzer timed out before sample reached LG 2.	Check sample cassette for clots. Run properly heparinized sample. Check peri pump cartridge and replace as necessary.
ERROR - Invalid Sample Discard Cassette <ENTER>	During OPTI-trol measurement, the sample detected was not a blood sample.	Measure a blood sample after OPTI-trol measurement.
WARNING Bad Sensor - pH Continue <ENTER> or <ESC> WARNING Bad Sensor - PCO2 WARNING Bad Sensor - PO2 WARNING Bad Sensor - Na WARNING Bad Sensor - K WARNING Bad Sensor - Ca WARNING Bad Sensor - Cl WARNING Bad Sensor - Glu	Air bubbles in cassette or void over sensor. Possible poor sample preparation or corrupt optics giving < 7,000 counts.	Check for air bubbles in cassette. Remix sample and rerun with new cassette. Cycle analyzer power. Open SMC cover and check operation of Blue LED's. Replace the SMC Assembly.
WARNING - Unstable pH Check Cassette WARNING - Unstable PCO2 WARNING - Unstable PO2 WARNING - Unstable Na WARNING - Unstable K WARNING - Unstable Ca WARNING - Unstable Cl WARNING - Unstable Glu	Possible poor sample preparation or air bubbles in cassette.	Check for air bubbles in cassette. Remix sample and rerun with new cassette.
WARNING – Gas Expires Soon!	Press YES to Continue	Gas will expire in two weeks.
WARNING - No Pat. ID Entry Continue <ENTER>	Patient ID is selected as a required entry	Press <ENTER> to continue and enter a Patient ID

Error Message	Possible Causes	Remedial Action
WARNING - No Op ID Entry Continue <ENTER>	Operator ID is selected as required entry	Press <ENTER> to continue and enter an Operator ID
WARNING - No ID Entry Continue <ENTER>	Patient and operator ID is selected as required entry.	Press <ENTER> to continue and enter a patient and operator ID.
WARNING No Sample Detected	Analyzer timed out before sample was detected by LG 1.	Reposition sample device and rerun sample.
WARNING - Check Pump Continue <ENTER> or <ESC>	LG1 and LG2 detected improper movement of buffer within cassette.	Open SMC and reseat cassette. Perform Flow Test in system diagnostics. Replace Pump Cartridge and seals. Check tubing for leaks.
WARNING - Check Pump Please remove cassette	If above message occurs repeatedly, this message is displayed.	Replace cassette.
No Display or power to analyzer	LCD display does not indicate analyzer operation.	Check if EPROM's are seated properly. Check fuses F1 and F3. Check for proper battery/charger power. Check cable connections.
Excessive use of gas	Possible leak in gas path.	Check for proper sealing of pump cartridge. Check for leak in tubing or tubing not connected. Clean seal in gas module assembly. Replace gas module.

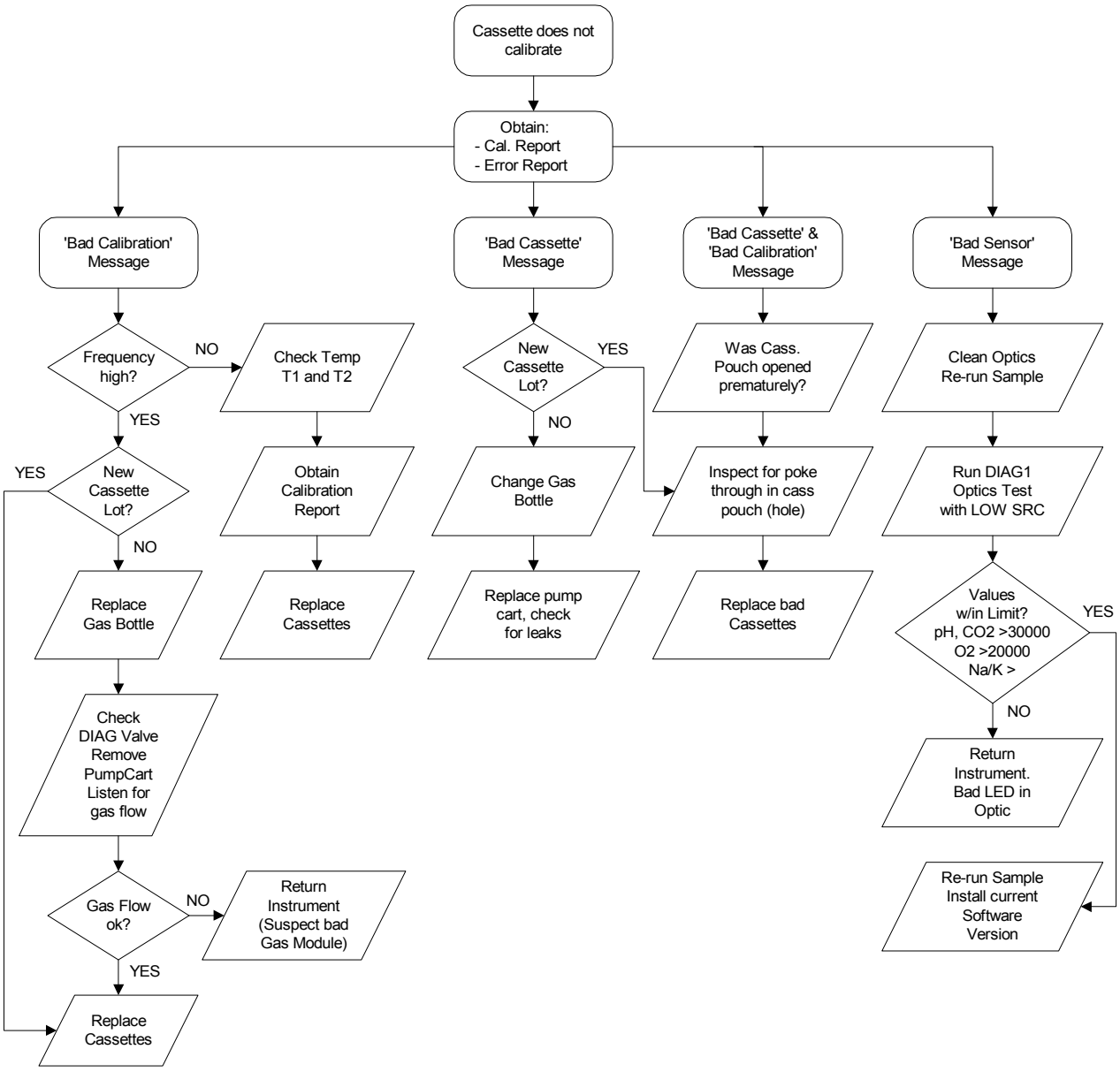
Error Message	Possible Causes	Remedial Action
New SRC Lot!	A new SRC is being run and has not been previously measured.	Print and delete previous SRC data prior to measuring new SRC.
Printer does not print	Possible printer paper jam or malfunction.	Check paper supply. Check printer for paper jams. Check printer cables for secure fit. Replace printer. Replace main board.
SRCs fail	Possible problem with Osmetech OPTI measurement system or SRC.	If Hb or SO_2 fails, perform Hb calibration, then delete SRC data and rerun. If only one SRC is failing, run QC samples. If QC is OK, replace SRC. If all SRCs are failing, reset unit and repeat measurements. Open the SMC cover. Verify three blue LED's are visible and steady. If not, replace the SMC cover. Replace the SMC module.
QC out of range	Possible problem with Osmetech OPTI measurement system.	Repeat QC measurement with new cassette ensuring that the cassette is wiped dry prior to measurement. If PCO_2 or PO_2 values are out, check the cassette for air bubbles or voids. Verify that the QC vial is not too warm or too cool before performing measurement. Replace calibration gas bottle.

Troubleshooting Flowcharts

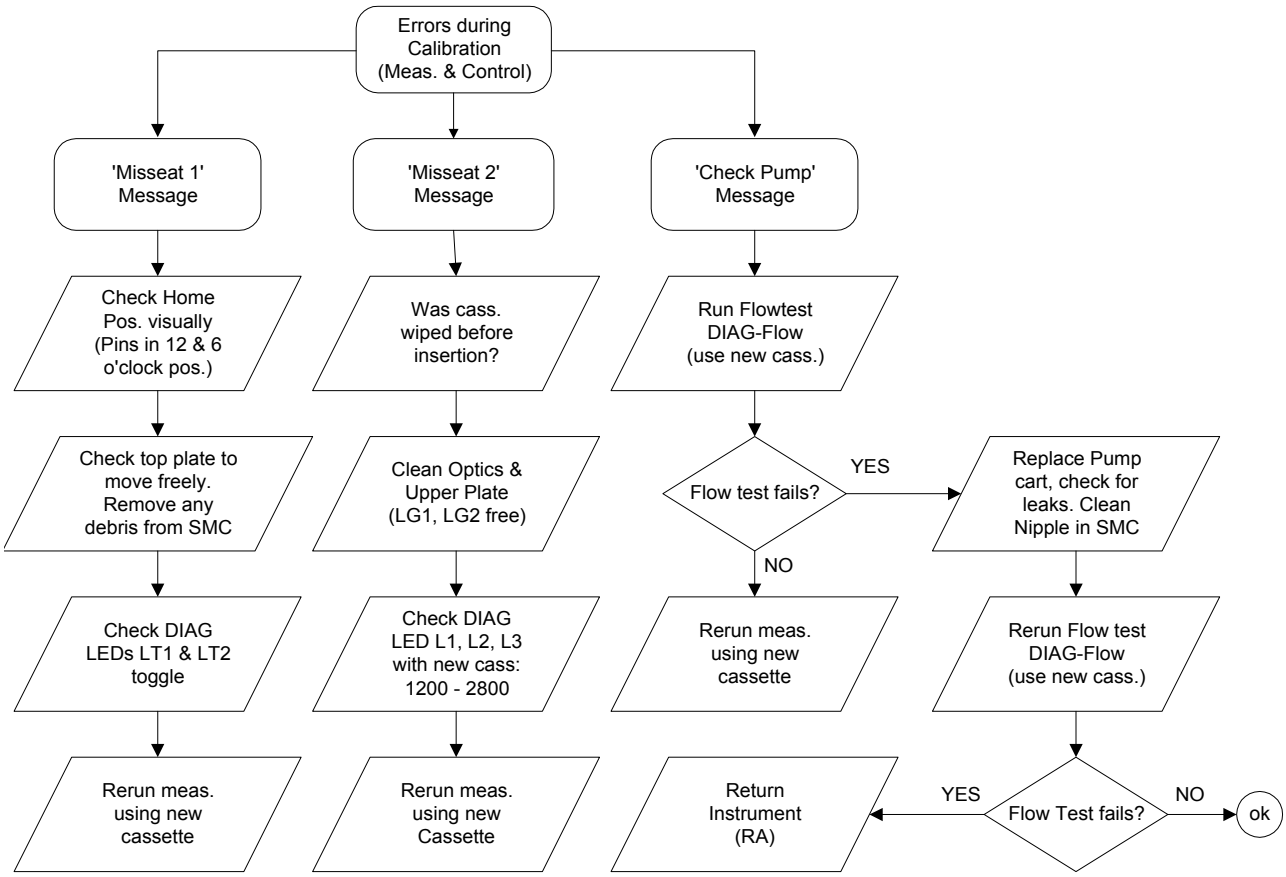
Osmetech OPTI Troubleshooting - 1


Instrument not READY or Lock-up / Freeze
Temperature Error Temp. High / Low
No Display or black squares on top line
BarCode Reader dead / Instrument locked-up / freeze
"System Error Cycle Power" Message
Wait 5 minutes for temp. to come into range
Connect to Power Supply
Cycle Power
Frequent Occurrence?
NO
Cycle Power (Initialize NOT necessary)
YES
Check for Room Temp to be 15-32°C
Check if EPROM's are seated correctly
Initialize Instrument (Feed & Cover)
Initialize Instrument (Feed & Cover)
Initialize Instrument (Feed & Cover)
Return Instrument (RA)
Replace Bar Code Reader
Return Instrument (RA)
or
Install Current Software version
Return Instrument (RA)
Return Instrument (RA)

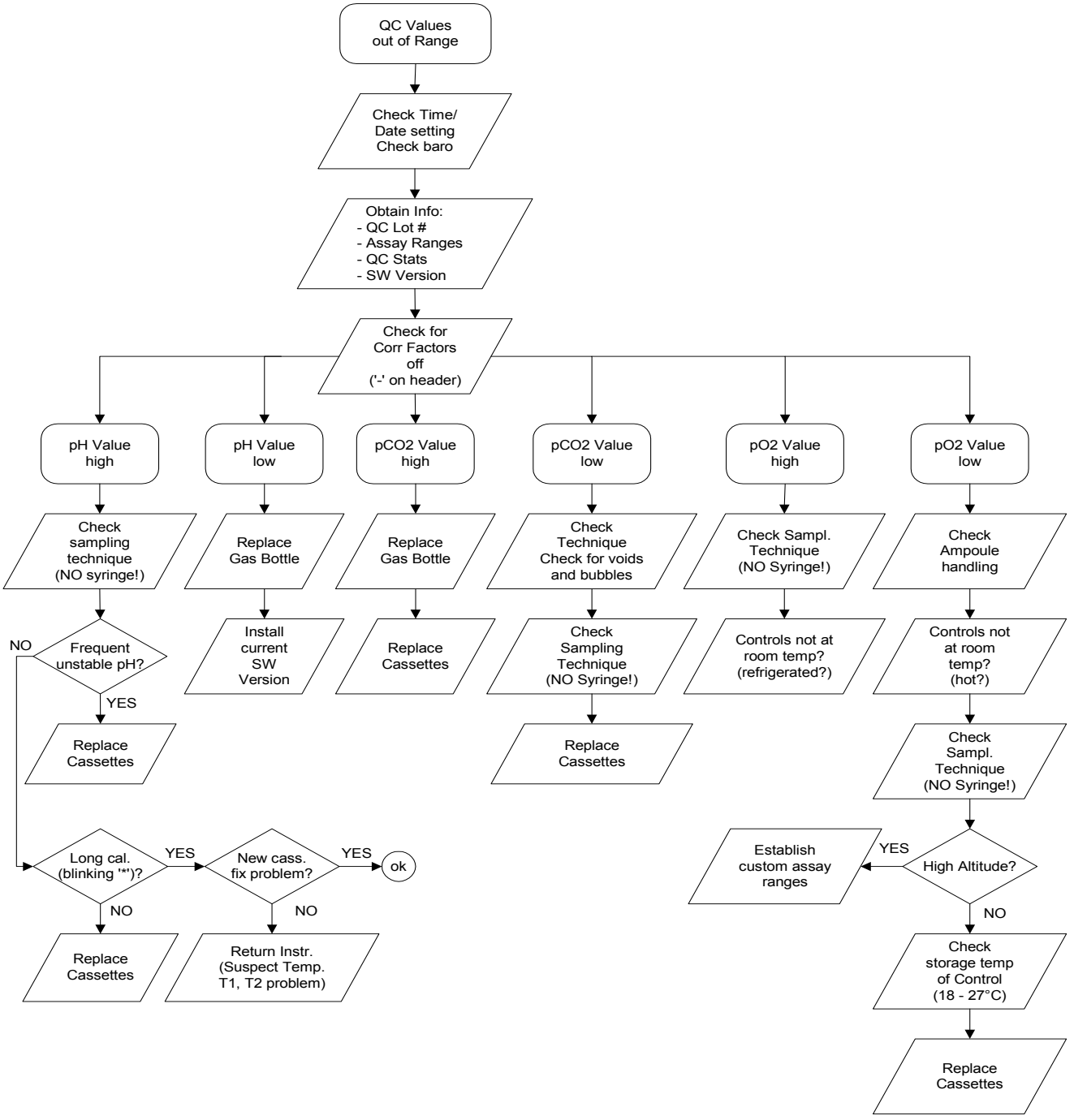
Osmetech OPTI Troubleshooting - 2



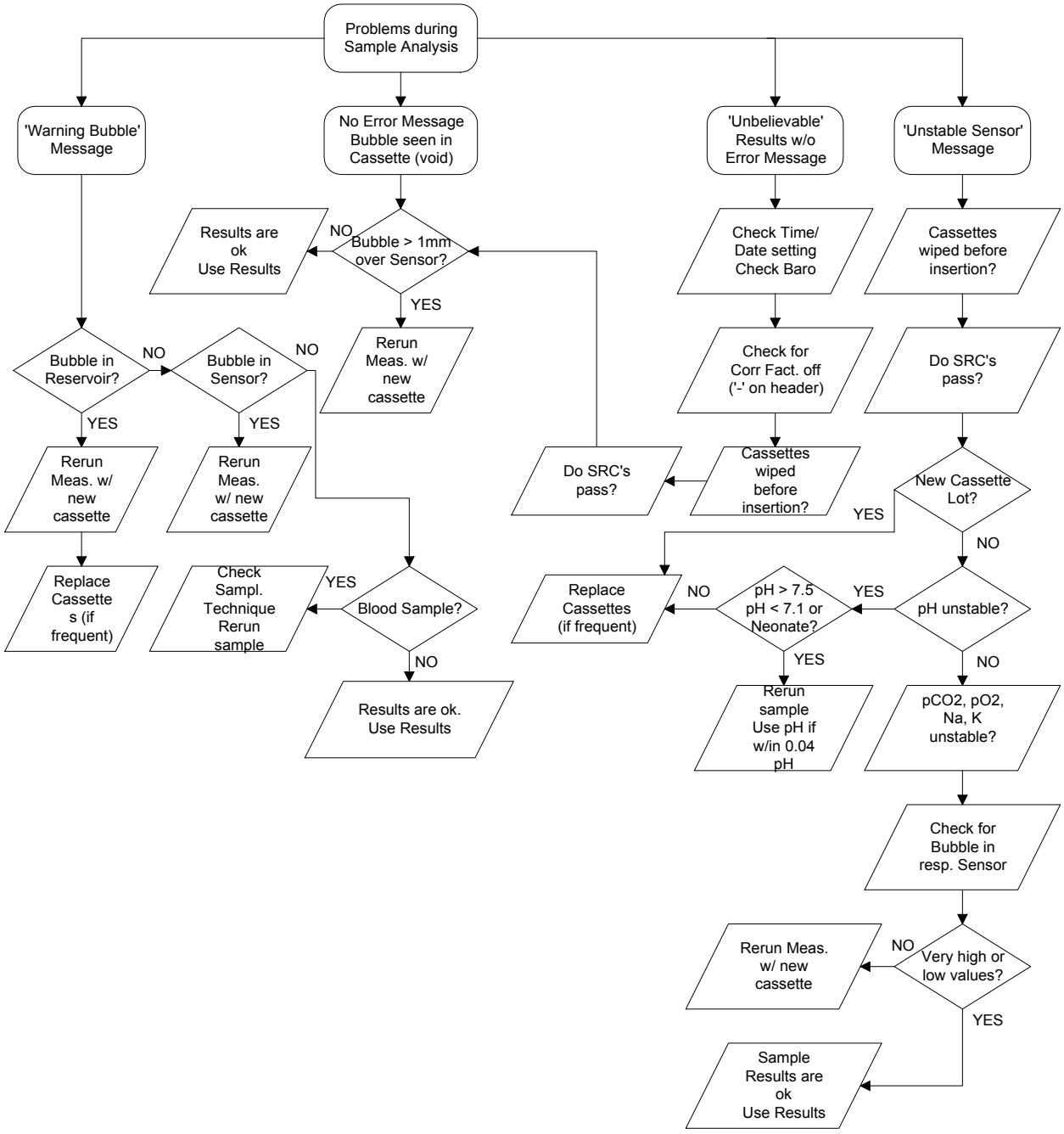
Osmetech OPTI Troubleshooting - 3


Errors during Calibration (Meas. & Control)
'Misseat 1' Message
'Misseat 2' Message
'Check Pump' Message
Check Home Pos. visually (Pins in 12 & 6 o'clock pos.)
Was cass. wiped before insertion?
Run Flowtest DIAG-Flow (use new cass.)
Check top plate to move freely. Remove any debris from SMC
Clean Optics & Upper Plate (LG1, LG2 free)
Flow test fails?
YES
Replace Pump cart, check for leaks. Clean Nipple in SMC
NO
Check DIAG LEDs LT1 & LT2 toggle
Check DIAG LED L1, L2, L3 with new cass: 1200 - 2800
Rerun meas. using new cassette
Rerun Flow test DIAG-Flow (use new cass.)
Rerun meas. using new cassette
Rerun meas. using new Cassette
Return Instrument (RA)
YES
Flow Test fails?
NO
ok

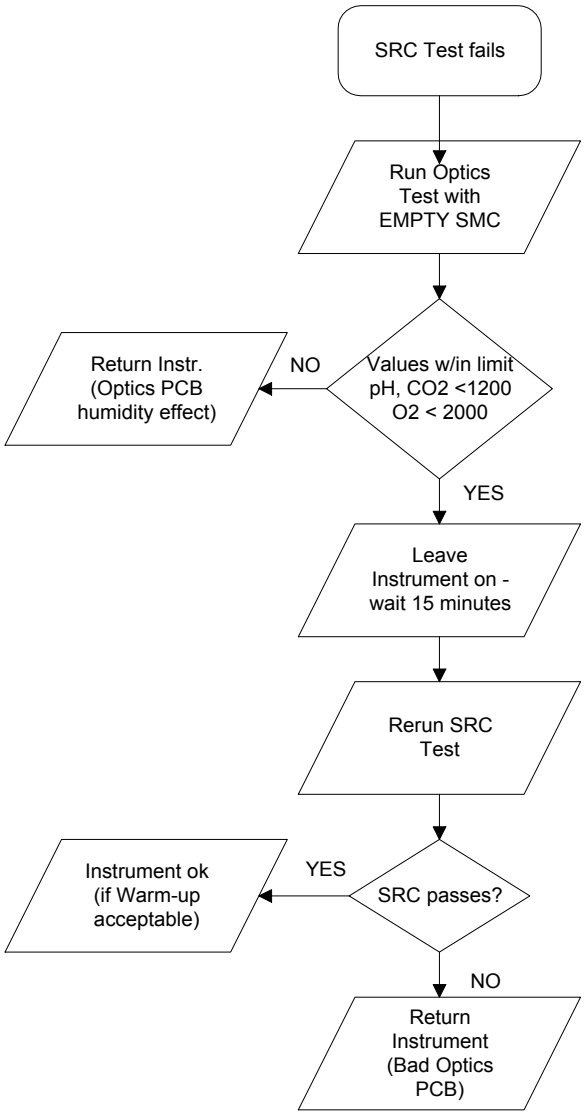
Osmetech OPTI Troubleshooting - 4



Osmetech OPTI Troubleshooting - 5



Osmetech OPTI Troubleshooting - 6



6 Osmetech OPTI™ Repair Procedures

The Osmetech OPTI series is categorized into 3 groups:

- Osmetech OPTI 1
- Osmetech OPTI CCA S/N <4000
- Osmetech OPTI CCA S/N >4000.

Please make sure to use the correct instrument category applicable to your instrument.

Osmetech OPTI™ 1 Systems

The Osmetech OPTI 1 is completely housed in a molded plastic case which provides a chassis for the electronic and mechanical assemblies. The analyzer is designed for quick removal of all major assemblies. Some of the components such as the printer, pump cartridge and top plate are accessible from the outside of the analyzer. The analyzer interior is accessible, after removing the bottom of the analyzer. The following chapter describes the removal of the major assemblies of the Osmetech OPTI 1.

Caution: Before disconnecting any analyzer assemblies disconnect the analyzer from primary power and remove the installed battery to avoid electrical damage

Pump Cartridge

Removal

The pump cartridge can be removed easily. Open the printer compartment cover to access the pump cartridge. Grasp the pump cartridge and pull straight up to free it from the pump motor shaft. The label on the pump cartridge contains the date of manufacture (DOM: WW – 2 digit calendar week; YY – 2 digit year).

The pump cartridge should be replaced if it is more than 12 months old.

Installation

To install the pump cartridge, first check whether the flat in the pump spool is aligned with the flat on the pump motor shaft. If is not aligned, a coin can be used to turn the spool within the pump cartridge housing to align the pump spool with the motor shaft. The motor shaft may also be turned for easier reinstallation of the pump cartridge. For easiest alignment of the motor shaft, turn the motor shaft so the flat on the motor shaft is parallel to the right side of the analyzer housing with motor shaft flat to the right.

Insert the pump cartridge and press down with a slight force so the cartridge fits onto the motor shaft and ensure the cartridge is seated into the pump ports. Press down on the pump spool to prevent the pump roller from binding on the pump cartridge housing, otherwise the pump will be noisy.

Verification

To break in the new pump, go to menu **DIAG1 – Gas** and continue to press **ENTER** to start a gas purge. Then go to **DIAG3 - Flow** to test the new pump cartridge. This test requires a cassette. It is allowable to use expired cassettes for this test. Before inserting the cassette, make sure the buffer in the cassette does not contain bubbles.

Press **ENTER** to start the test. In case the pump test fails, repeat the test.

In case of 3 subsequent failures, replace the pump cartridge.

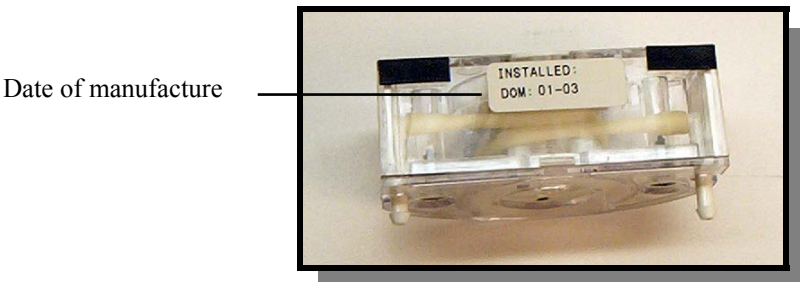


Figure 1: Peristaltic pump cartridge

Printer Assembly

Removal

To remove the printer assembly, first open the printer cover to gain access to the printer assembly. Remove the pump cartridge to allow enough free space for removing the printer assembly without interference in the printer compartment. The pump cartridge can be removed by grasping it and pulling it up.
Next remove the printer paper and set aside. Two thumb screws which hold the printer assembly in place can now be loosened – see Figure below. After the thumb screws have been loosened, the printer can be slid towards the rear of the analyzer. Disconnect the printer ribbon cable that attaches to the printer.
The printer assembly can now be removed.

In case the printer mechanism is replaced, unscrew the printer shroud and loosen the four (4) screws holding the printer to the PCB.

Disconnect the flex cable from the receptacle.

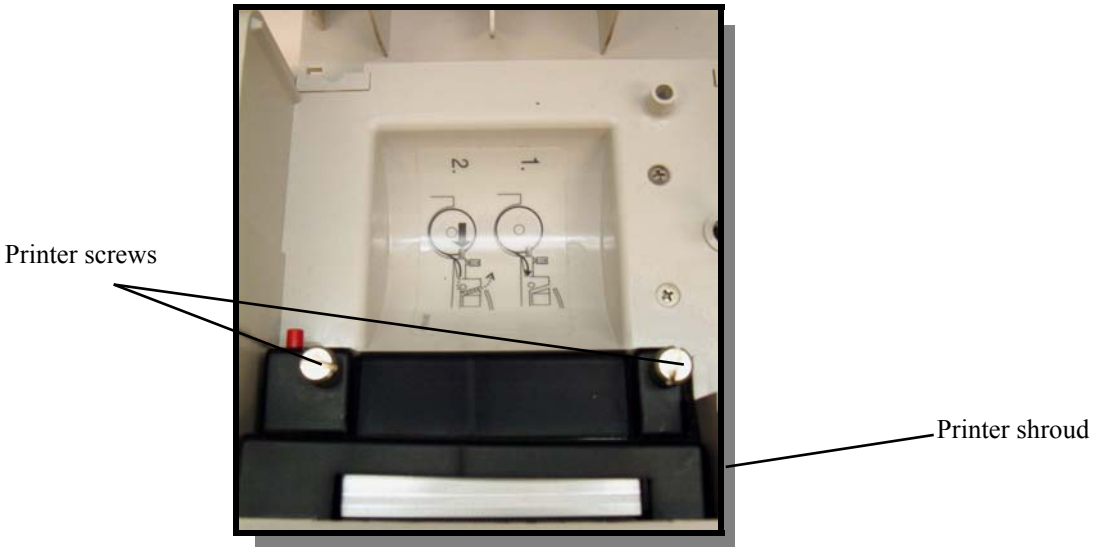


Figure 2: Printer assembly screws

Installation

The printer is installed in reverse sequence to removal.

Note: Jumper JP1 on the printer board has no function.

In case a new printer mechanism is installed, remove the white transport clip from the printer mechanism. Then install the printer in reverse order of removal. Make sure the flex cable is plugged in all the way.

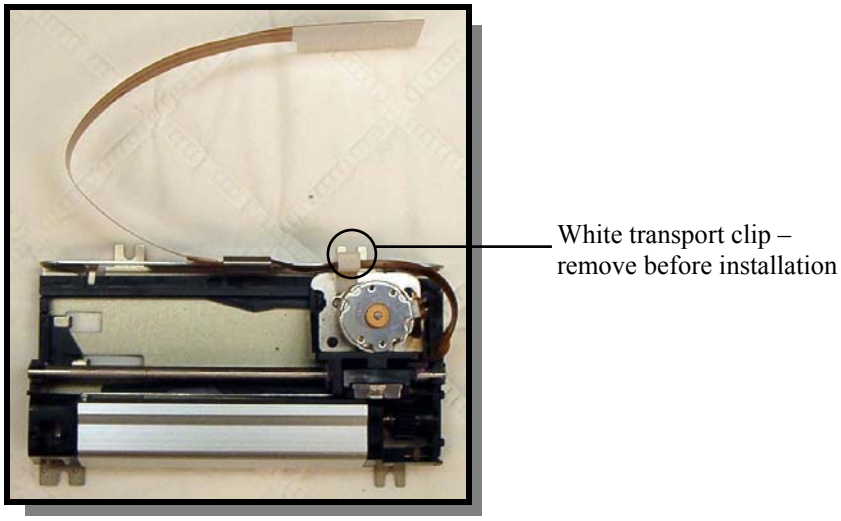


Figure 3: Printer mechanism with transport clip

Printer trouble shooting

If the printer is...	Then…
Missing dots or not printing properly **or** **Not moving or operating, but instead is 'buzzing'**	• Remove the printer shroud (two small screws on bottom of printer). • Clean off all dust and dirt accumulation – make sure all foreign debris is removed from the gear tracks and paper advance lever. • Lightly grease the silver guide rod as well as the paper advance lever. **Use silicon grease only.** • After completing these steps, recheck the printer. • If the printer still does not work. Replace the printer mechanism.

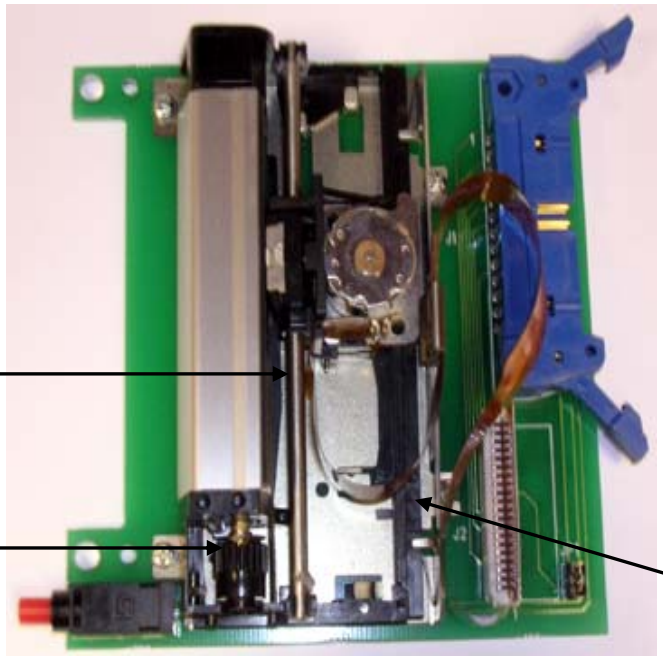

Clean and grease guide bar (silicon grease only)
Remove all debris from paper advance lever, grease if necessary
Remove all debris from printer gear track.
Paper advance levers
Guide rod

Figure 4: Printer assembly

Verification

Go to menu **DIAG 2 - Printr** and perform a test print.

Analyzer Housing

The main analyzer housing is comprised of two (2) parts, the lower and upper housing. The assemblies located inside the analyzer can be removed. To gain access to these assemblies, the analyzer housings must be separated. To open the analyzer housing, first remove the battery on the left side of the analyzer. Turn the analyzer over to access the seven (7) screws securing the two housing sections together. Remove the screws and separate the upper and lower housing sections by flipping the lower housing open on the side of the carrying handle.

Caution: When turning the analyzer over to access the lower housing section, place the analyzer on a padded surface to prevent scratches or other damage to the upper housing section.

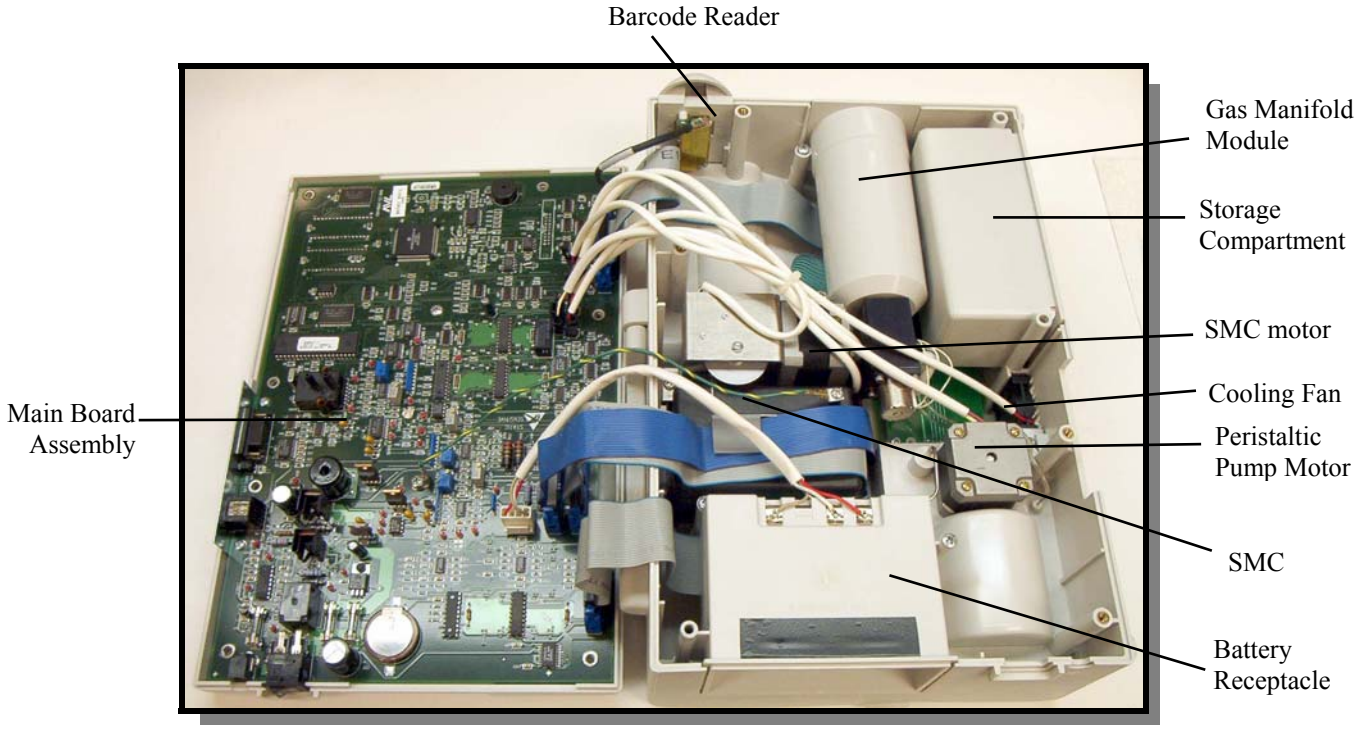


Figure 5: Opened Osmetech OPTI 1 Analyzer

Sample Measurement Chamber (SMC) Cover

Important Note

The SMC cover can only be replaced by a trained service technician.

SMC Lower Module

Important Note

The SMC module can only be replaced by a trained service technician.

Osmetech OPTI 1 Handle

The Osmetech OPTI 1 is equipped with a carrying handle for easy transport. To remove the handle, first separate the lower portion of the analyzer. To access the handle, remove the battery compartment, gas manifold module and storage compartment (See the respective sections for removal instructions). Next remove the four (4) self-tapping screws which hold the handle in place.

Pump Nipples

In case the pump nipples are damaged they need to be replaced. Damage usually occurs during removal of the pump receptacles. To remove damaged nipples, remove the pump cartridge and the pump receptacles. Open up the instrument, disconnect the tubes from the nipples and cut the nipples off flush with the housing (See Operator's Manual for pump receptacle removal procedures). Pull the remainder of the nipple out through the topside of the housing. The new nipples are inserted from the back of the housing with the large end pushed through the housing. To seat the nipples, use a suitable tool (small pliers) press hard against the base of the nipple, until it clicks in place.

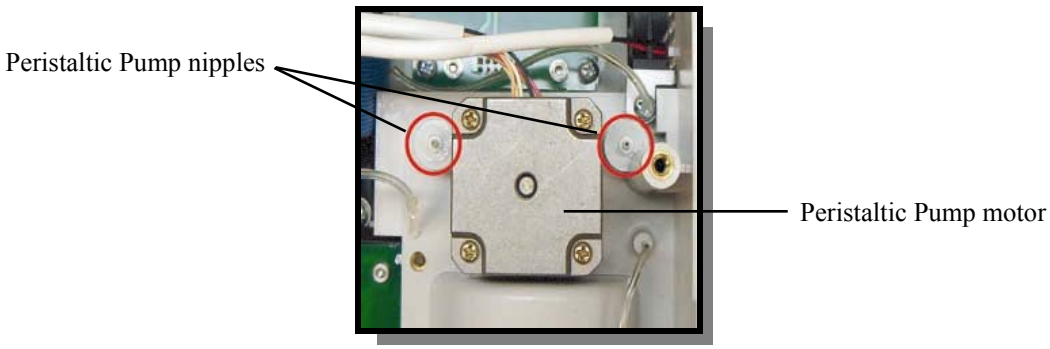


Figure 6: Peristaltic pump nipple connectors

Gas Manifold Module

Removal

The gas manifold module is located on the right rear side of the analyzer. The calibration gas cylinder is screwed into the module to form a gas-tight seal. The gas manifold module provides pressure regulation and controls the flow of gas when required for cassette calibration. To remove the module, first open the lower portion of the analyzer. Disconnect the Tygon tubes which connect to the peristaltic pump and clean-out port.

Next disconnect the cable connectors J11 on the Main Board. The module is held in place by two (2) screws. After removal of these screws, the module may be pulled out of the analyzer.

To replace the Lee valve, desolder the wires from the old valve.

To remove the Aerodyne gas module, remove the two (2) screws holding the gas manifold to the plastic housing.

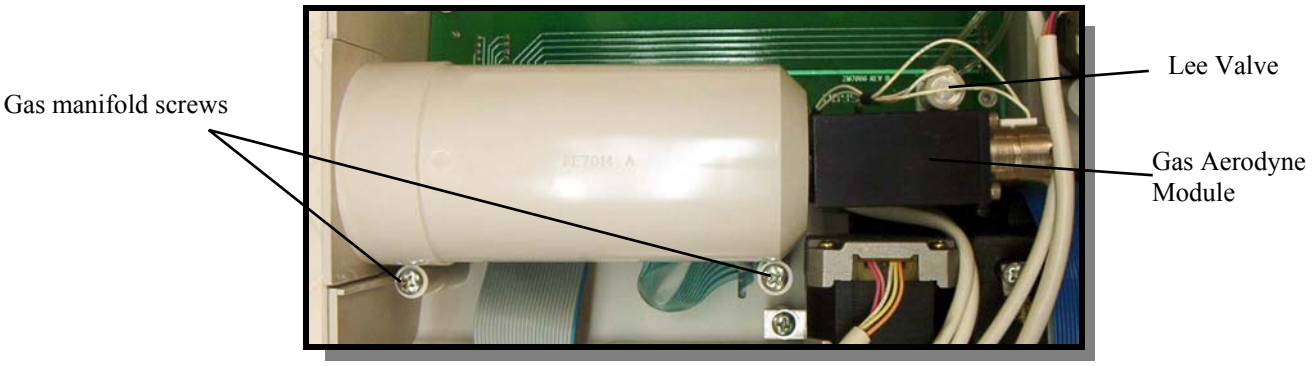


Figure 7: Gas manifold module

Installation

Upon reassembly, make sure the tubes from the clean-out port and the peristaltic pump are connected to the correct nipples and the cable connector is reconnected to the main board. The tubes should *not* be crossed.

To add a new Lee valve, resolder the wires of the new valve to the harness. The valve is not polarized. Add LockTite to the mounting screws. Do not over tighten the screws, since this may damage the valve.

To re-install the Aerodyne module, you must use **new** screws, DS7000. The screws must be tightened such that the two black rubber pads are compressed to a thickness of 1.6mm. Use a feeler gauge to check the compression.

Verification

To test the gas module proceed as follows:

- Insert the gas bottle into the OPTI to be tested. Power on the unit.
- Go to **DIAG3 – GValve** and press **ENTER**. This will activate the gas valves and pressurize the entire gas system including the pump cartridge.
- Toggle the GValve on/off and listen for a 'click' sound from the activating valve.

To test the **Aerodyne module output flow**, proceed as follows:

- Take a **full** gas bottle and insert the bottle into the OPTI.
- Go to **DIAG3 – GValve** and press **ENTER**. Press the right arrow key to de-activate the gas valves.
- Remove the pump cartridge.
- Press the left arrow key once and listen for gas coming out the rear pump port. Press the left arrow key right away to deactivate the gas valve.
- If you cannot hear the gas flow, the gas manifold module needs to be replaced.

Display Assembly

Removal

The Osmetech OPTI 1 uses a backlit LCD display module to display operating instructions and analyzer results. To remove the LCD display, first open the lower portion of the analyzer and disconnect the ribbon cables J13 on the main board. The storage compartment and gas manifold module must also be removed. Disconnect the keyboard cable. Next remove the four (4) screws which hold the LCD display assembly in place. The assembly can now be removed.

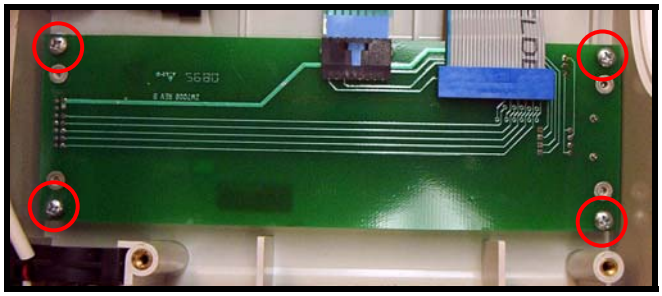


Figure 8: LCD Back panel, fastening screws are circled

Installation

To reinstall the assembly, follow the removal instructions in reverse order. Before tightening the mounting screws, make sure to center the display over the window.

Verification

To test the display go to **DIAG2 – Displ** and press **ENTER**. Check if all dots are dark. If dots remain blank, the display assembly must be replaced.

Keypad

Removal

The keypad on the Osmetech OPTI 1 can be removed by first opening the lower portion of the analyzer. The flex cable from the keypad will now need to be disconnected from the display board. Use a knife to lift off the keypad from the analyzer housing.

Installation

Before replacement with a new keypad, the surface must be cleaned. Use alcohol to remove any adhesive which may be on the surface. The surface must be clean and dry before installing a new keypad. Take the new replacement keypad and remove the backing to expose the adhesive side of the keypad. Connect the keypad cable to the display board. Feed the cable through the slot in the analyzer housing. Carefully apply the new keypad to ensure proper alignment on the analyzer housing.

Caution: The keypad is attached to the housing of the analyzer with an adhesive backing and can not be re-used once removed from the analyzer.

Verification

To test the keypad go to **DIAG2 - Keypd** and press **ENTER**. Check if all the buttons result in the correct response. The keypad must be replaced in case of any malfunction or sluggish response.

Exhaust Fan

Removal

The Osmetech OPTI 1 is equipped with an internal exhaust fan which is used for cooling the electronic circuitry.

The fan is controlled by the software. T3 measures the air temperature inside the OPTI housing and is displayed in the **DIAG1 - Temp** menu. If T3 rises above 31.5 ° C, the fan is activated. If T3 drops below 30.5 ° C, the fan turns off.

To remove the fan, first open the lower portion of the analyzer. Disconnect connector J10 which attaches to the main board. Remove one (1) or two (2) screws of the fan retainer. Next remove the retainer and slide the fan out of the analyzer.

Installation

Install the new fan in reverse order.

Verification

To test the fan go to **DIAG1 – Temp** and press **ENTER**. Allow the instrument to warm-up so that T3 exceeds 32 degrees Celsius or until the fan turns on. Verify the proper fan operation by holding your hand over the rear vent covers. The fan will pull air through the air vents located on the bottom cover across the main board circuitry and through the cooling fan vent. An outward air flow should be felt at the cooling van vent. In case no air flow is felt, look through the vent cover to check if the fan blades turn. If the fan does not turn in full rotations or is noisy, then the fan must be replaced. A properly working fan should operate quietly and quickly cool the internal OPTI circuitry.

Storage Compartment

Located on the rear panel of the Osmetech OPTI 1 is a storage compartment used for storing accessories during transport. To disassemble the storage compartment:

- First separate the lower portion of the analyzer
- Then, slide the storage compartment out of the upper housing.

To replace the storage compartment, fit the grooved edges of the compartment over the upper housing and slide it into place. Each OPTI 1 should have one Level 1 SRC and one Level 3 SRC.

Peristaltic Pump Motor

Removal

The peristaltic pump assembly is comprised of the pump motor and the peristaltic pump cartridge. During operation the peristaltic pump provides the necessary pump flow to move reagents, calibration gas and samples.
The peristaltic pump uses a stepper motor which is controlled by the main board and turns the pump roller in the pump cartridge to generate a small vacuum.
To remove the pump motor:

- Open the lower portion of the analyzer housing for access to the pump motor assembly and disconnect the pump motor cable **J9** from the main board.
- Open the printer cover and remove the pump cartridge.
- Open the printer cover and remove the four (4) pump motor mounting screws, accessed from the top (see Figure below).
- Remove the peristaltic pump motor by sliding the assembly out from the lower portion of the analyzer housing.

Figure 9: Peristaltic pump motor mounting screws (circled)

Installation

Install the peristaltic pump motor in reverse order.

Verification

To test the pump motor go to **DIAG3 – Pump** and press **ENTER**. The pump should turn counterclockwise for a brief moment, and then it should switch clockwise and rotate smoothly, without excessive noise through all speeds.
If any of these conditions are not met the pump motor must be replaced.

Important Note

In case the pump hesitates on the fast speed, replace the pump cartridge and repeat the test.

Battery Receptacle

Removal

The Osmetech OPTI can be operated by either battery or by AC power.
To remove the battery receptacle, first remove the battery from the analyzer. The lower housing portion of the analyzer must be opened for access. Locate the battery receptacle and disconnect the internal cable **J4** from the main board. Next remove the two (2) retaining screws and pull the receptacle out of the analyzer.

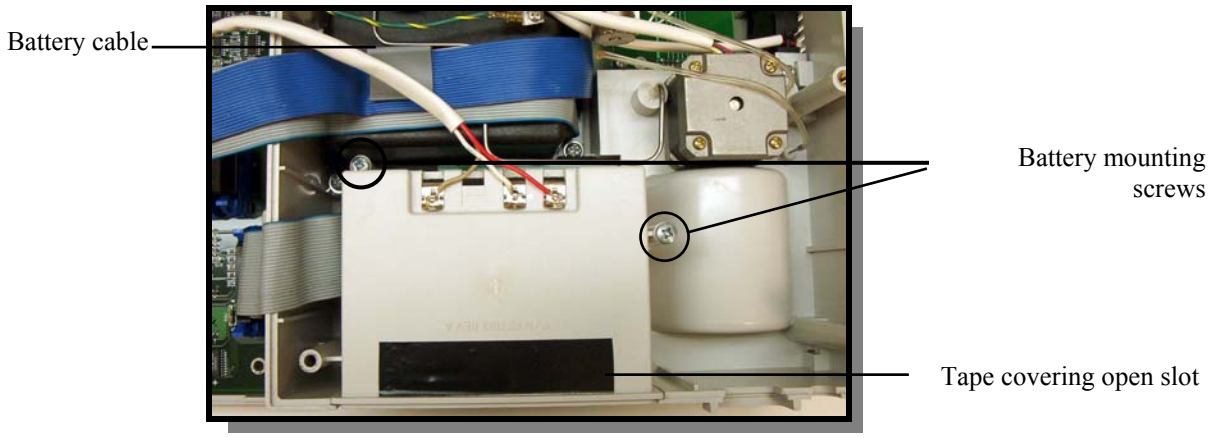


Figure 10: Battery receptacle screws (circled)

Installation

Follow the reverse order to install the new battery receptacle. Make sure the tape covering the bottom slots is in place (See Figure above).

Verification

To test the battery receptacle remove the battery. Turn the instrument on, powered by the power supply. Check the battery charge LED on the backside of the instrument. The LED should be off. As the battery is inserted the LED should start blinking fast (4 times per second) or come-on solid. If this test passes, disconnect the power cord and verify that the instrument continues to operate.

Important Note

This part of the test requires a charged battery.

Figure 11: Location of the battery charge LED (circled)

Main Board Assembly

Important Note

The main board can only be replaced by a trained service technician.

Important Note

BT1 is a rechargeable lithium battery. In case this battery needs replacement, make sure to replace with the same type, Panasonic VL3032.

Caution: Danger of explosion, if battery is incorrectly replaced. Replace only with type Panasonic VL3032. Follow local regulations for disposal.

Barcode Reader

Removal

The internal barcode reader assembly is used to read the barcode data supplied with each cassette and Standard Reference Cassette (SRC). To access the internal barcode reader, first separate the upper and lower analyzer housing sections. Locate the barcode reader guide. Push on the latch and slide the guide downward. The module is held in place by retaining screws which must be removed. Disconnect cable **J14** from the main board. Pry out the window of the barcode reader with a screw driver and remove the assembly.

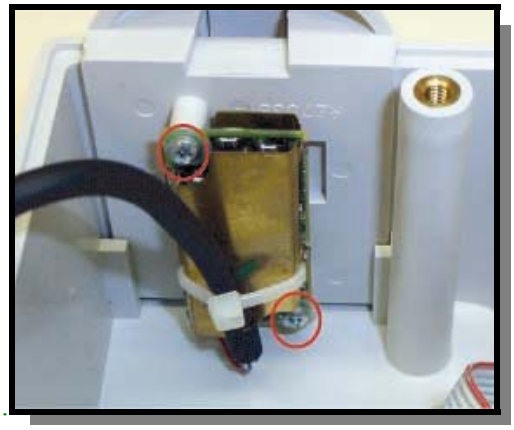


Figure 12: Barcode reader and screws (circled);

Barcode reader guide on opposite side of barcode reader module

Installation

Install the barcode reader module in reverse order. Make sure the replacement barcode reader has the copper foil around the black barrel as well as a cable tie to serve as a strain relief. Otherwise transfer these items from the old barcode reader before installation.

Verification

Go to **DIAG2 – BCode** and swipe a cassette barcode. The cassette barcode should appear on the display screen.
Note: the displayed barcode is preceded by one additional character (signifies barcode type).

Osmetech OPTI™ CCA Systems S/N <4000

The Osmetech OPTI™ CCA is completely housed in a molded plastic case which provides a chassis for the electronic and mechanical assemblies.
The analyzer is designed for quick removal of all major assemblies. Some of the components such as the printer, pump cartridge and top plate are accessible from the outside of the analyzer. The analyzer interior is accessible, after removing the bottom of the analyzer. The following chapter describes the removal of the major assemblies of the Osmetech OPTI CCA S/N <4000.

Caution: Before disconnecting any analyzer assemblies, disconnect the analyzer from primary power and remove the installed battery to avoid electrical damage

Pump Cartridge

Removal

The pump cartridge can be removed easily. Open the printer compartment cover to access the pump cartridge. Grasp the pump cartridge and pull straight up to free it from the pump motor shaft. The label on the pump cartridge contains the date of manufacture (DOM: WW – 2 digit calendar week; YY – 2 digit year – see Figure 13).

The pump cartridge should be replaced if it is more than 12 months old.

Installation

To install the pump cartridge, first check whether the flat in the pump spool is aligned with the flat on the pump motor shaft. If the flat on the pump spool is not aligned, a coin can be used to turn the spool within the pump cartridge housing and align the pump spool with the motor shaft. The motor shaft may also be turned for easier reinstallation of the pump cartridge. For easiest alignment of the motor shaft, turn the motor shaft so the flat on the motor shaft is parallel to the right side of the analyzer housing with motor shaft flat to the right. Insert the pump cartridge and press down with a slight force so the cartridge fits onto the motor shaft and ensure the cartridge is seated into the pump ports.
Press down on the pump spool to prevent the pump roller from binding on the pump cartridge housing, otherwise the pump will be noisy.

Verification

To break in the new pump, go to menu **DIAG1 – Gas** and continue to press **ENTER** to start a gas purge. Then go to **DIAG3 - Flow** to test the new pump cartridge. This test requires a cassette. It is allowable to use expired cassettes for this test. Before inserting the cassette, make sure the buffer in the cassette does not contain bubbles.

Press **ENTER** to start the test. In case the pump test fails, repeat the test.

In case of 3 subsequent failures, replace the pump cartridge.

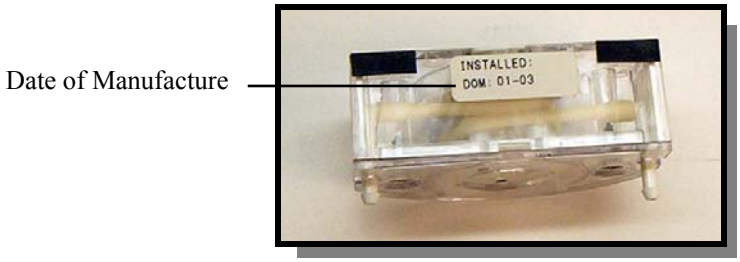


Figure 13: Peristaltic pump cartridge

Printer Assembly

Removal

To remove the printer assembly, first open the printer cover to gain access to the printer assembly. Remove the pump cartridge to allow enough free space for removing the printer assembly without interference in the printer compartment. The pump cartridge can be removed by grasping it and pulling it up.
Next remove the printer paper and set aside. Two thumb screws which hold the printer assembly in place can now be loosened – see Figure below. After the thumb screws have been loosened, the printer can be slid towards the rear of the analyzer. Disconnect the printer ribbon cable that attaches to the printer.
The printer assembly can now be removed.

In case the printer mechanism is replaced, unscrew the printer shroud and loosen the four (4) screws holding the printer to the PCB.

Disconnect the flex cable from the receptacle.

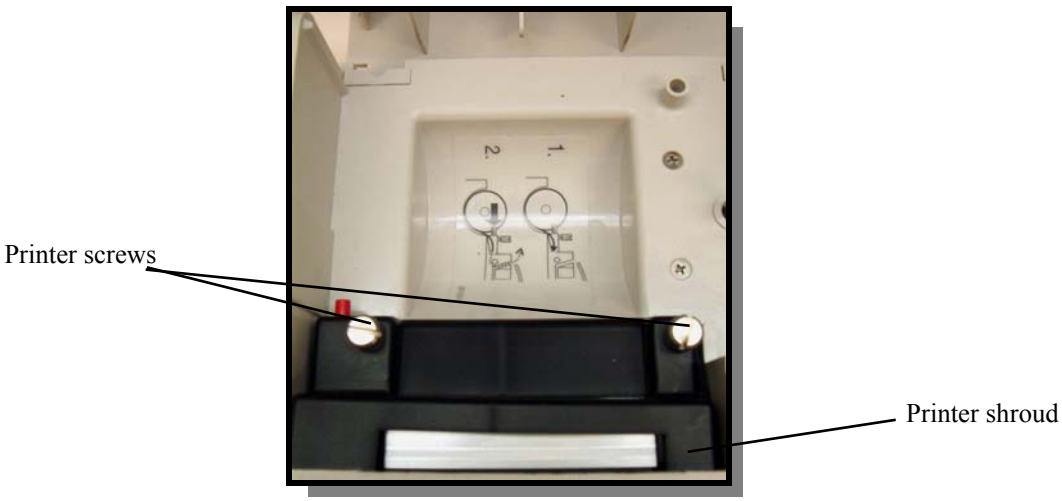


Figure 14: Printer assembly screws

Installation

The printer is installed in reverse sequence to removal.

Note: Jumper JP1 on the printer board has no function.

In case a new printer mechanism is installed, remove the white transport clip from the new printer mechanism. Then install the printer in reverse order of removal. Make sure the flex cable is plugged in all the way.

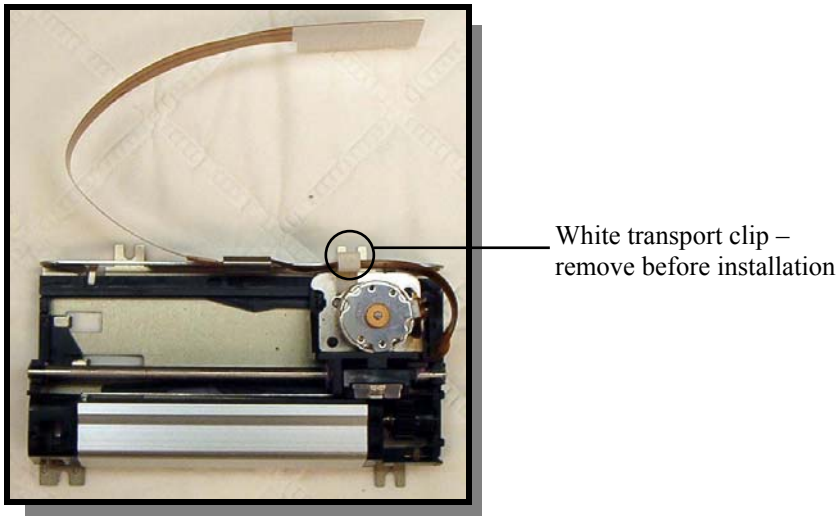


Figure 15: Printer mechanism with transport clip

Printer trouble shooting

If the printer is...	Then…
Missing dots or not printing properly **or** **Not moving or operating, but instead is 'buzzing'**	• Remove the printer shroud (two small screws on bottom of printer). • Clean off all dust and dirt accumulation – make sure all foreign debris is removed from the gear tracks and paper advance lever. • Lightly grease the silver guide rod as well as the paper advance lever. **Use silicon grease only.** • After completing these steps, recheck the printer. • If the printer still does not work. Replace the printer mechanism.

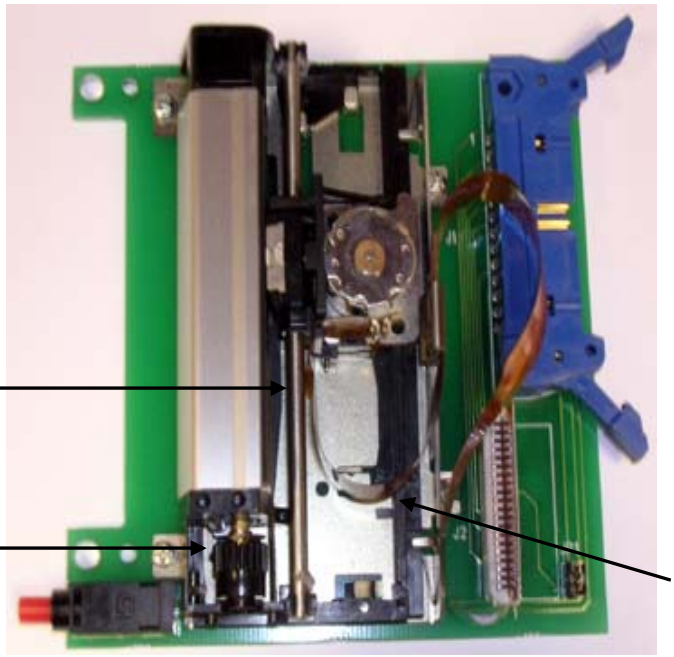

Clean and grease guide bar
(silicon grease only)
Remove all debris from paper
advance lever, grease if necessary
Remove all debris from printer gear track.

Figure 16: Printer assembly

Verification

Go to menu **DIAG2 - Printr** and perform a test print.

Analyzer Housing

The main analyzer housing is comprised of two (2) parts, the lower and upper housing. The assemblies located inside the analyzer can be removed. To gain access to these assemblies, the analyzer housings must be separated. To open the analyzer housing, first remove the battery on the left side of the analyzer. Turn the analyzer over to access the seven (7) screws securing the two housing sections together. Remove the screws and separate the upper and lower housing sections by flipping the lower housing open on the side of the carrying handle.

Caution: When turning the analyzer over to access the lower housing section, place the analyzer on a padded surface to prevent scratches or other damage to the upper housing section.

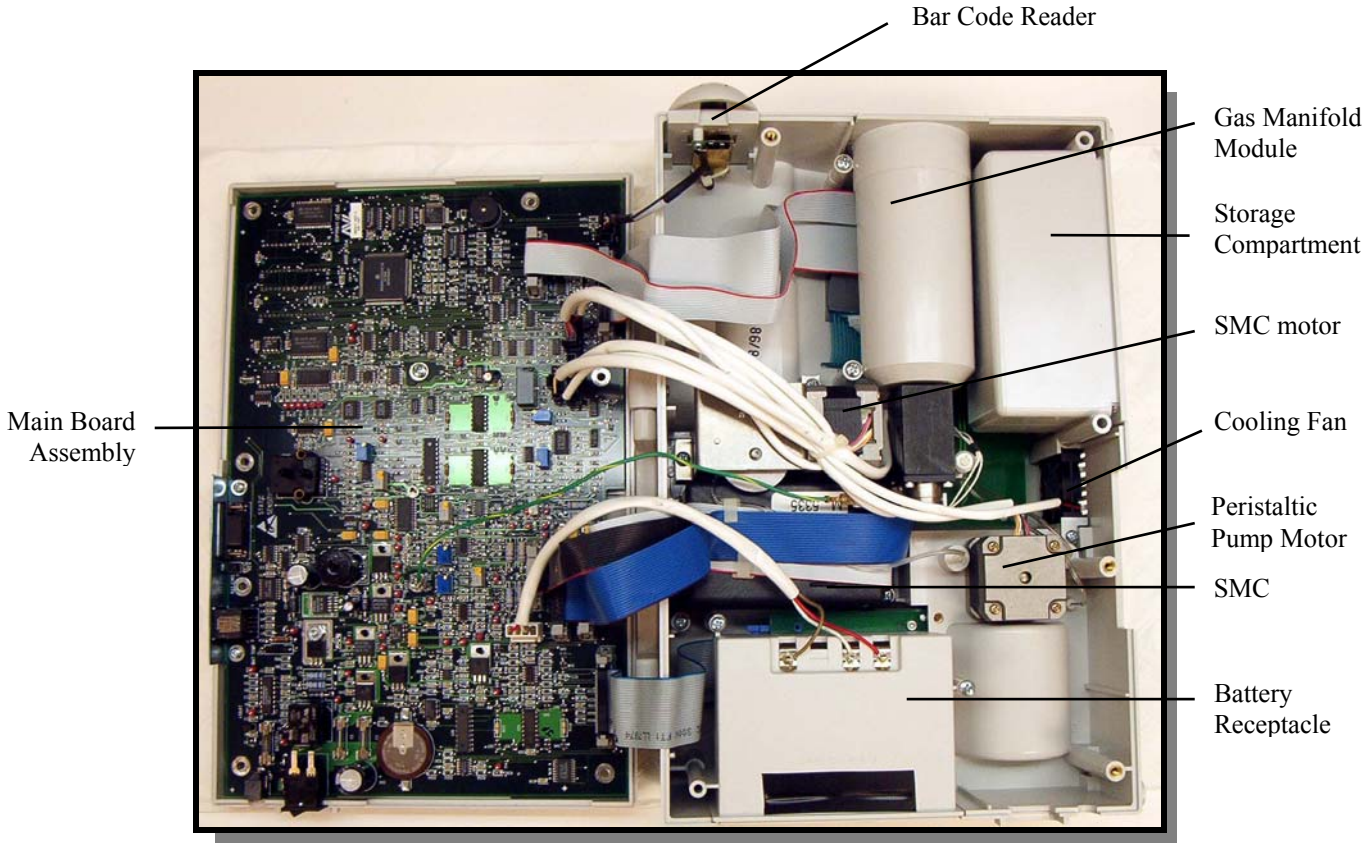


Figure 17: Opened Osmetech OPTI CCA Analyzer

Sample Measurement Chamber Cover

Important Note

The SMC cover cannot be replaced due to the necessary tHb and SO2 calibration, which can only be performed by the manufacturer.

SMC Lower Module

Important Note

The SMC module can only be replaced by a trained service technician.

Osmetech OPTI CCA Handle

The Osmetech OPTI CCA is equipped with a carrying handle for easy transport. To remove the handle, first separate the lower portion of the analyzer. To access the handle, remove the battery compartment, gas manifold module and storage compartment (See the respective sections for removal instructions).
Next remove the four (4) self-tapping screws which hold the handle in place.

Pump Nipples

In case the pump nipples are damaged they need to be replaced. Damage usually occurs during removal of the pump receptacles. To remove damaged nipples, remove the pump cartridge and the pump receptacles open up the instrument, disconnect the tubes from the nipples and cut the nipples off flush with the housing (See Operator's Manual for pump receptacle removal procedures). Pull the remainder of the nipple out through the topside of the housing. The new nipples are inserted from the back of the housing with the large end pushed through the housing. To seat the nipples, use a suitable tool (small pliers) press hard against the base of the nipple, until it clicks in place.

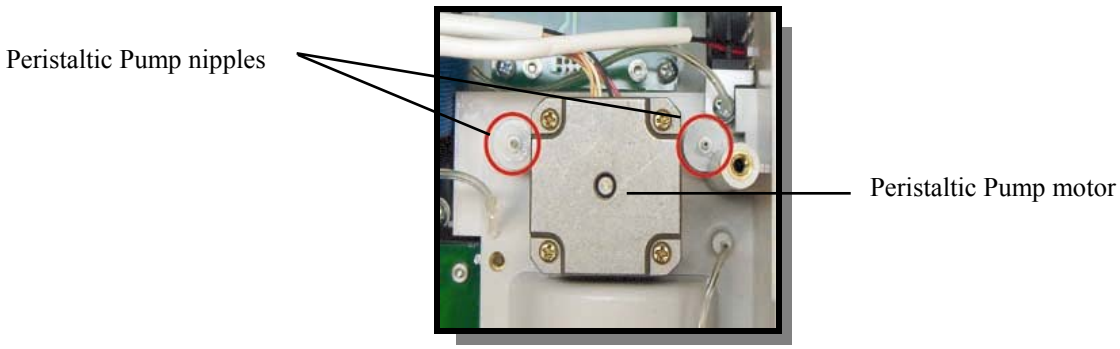


Figure 18: Peristaltic pump nipple connectors

Gas Manifold Module

Removal

The gas manifold module is located on the right rear side of the analyzer. The calibration gas cylinder is screwed into the module to form a gas-tight seal. The gas manifold module provides pressure regulation and controls the flow of gas when required for cassette calibration. To remove the module, first open the lower portion of the analyzer. Disconnect the Tygon tubes which connect to the peristaltic pump and clean-out port. Next disconnect the cable connector J9 on the Main Board. The module is held in place by two (2) screws. After removal of these screws, the module may be pulled out of the analyzer.

To replace the Lee valve, desolder the wires from the old valve.

To remove the Aerodyne gas module, remove the two (2) screws holding the gas manifold to the plastic housing.

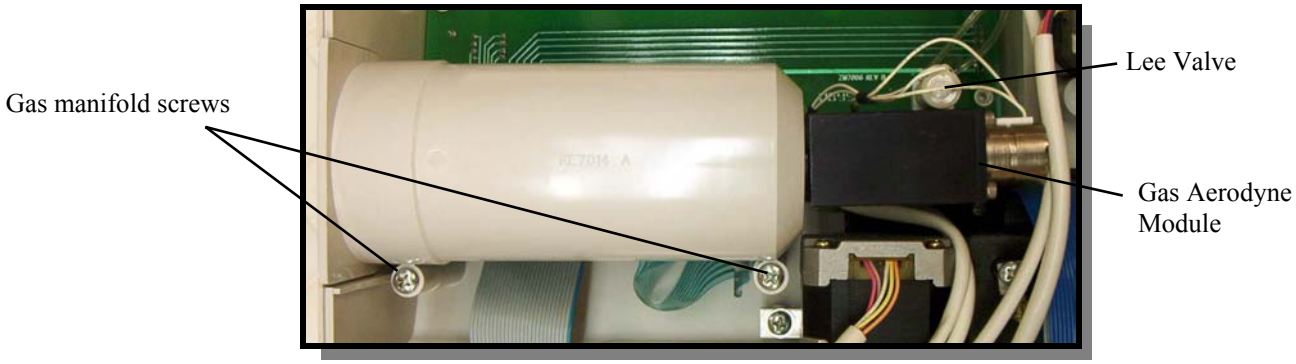


Figure 19: Gas manifold module

Installation

Upon reassembly, make sure the tubes from the clean-out port and the peristaltic pump are connected to the correct nipples and the cable connector is reconnected to the main board. The tubes should *not* be crossed.

To add a new Lee valve, resolder the wires of the new valve to the harness. The valve is not polarized. Add LockTite to the mounting screws. Do not over tighten the screws, since this may damage the valve.

To re-install the Aerodyne module, you must use **new** screws DS7000. The screws must be tightened such, that the two black rubber pads are compressed to a thickness of 1.6mm. Use a feeler gauge to check the compression.

Verification

To test the gas module proceed as follows:

- Insert the bottle into the Osmetech OPTI to be tested. Power on the unit.
- Go to **DIAG3 – GValve** and press **ENTER**. This will activate the gas valves and pressurize the entire gas system including the pump cartridge.
- Toggle the GValve on/off and listen for a 'click' sound from the activating valve.

To test the **Aerodyne module output flow**, proceed as follows:

- Take a **full** gas bottle and insert the bottle into the Osmetech OPTI.
- Go to **DIAG3 – GValve** and press **ENTER**. Press the right arrow key to de-activate the gas valves.
- Remove the pump cartridge.
- Press the left arrow key once and listen for gas coming out the rear pump port. Press the left arrow key right away to deactivate the gas valve.
- If you cannot hear the gas flow, the gas manifold module needs to be replaced.

Display Assembly

Removal

The Osmetech OPTI CCA uses a backlit LCD display module to display operating instructions and analyzer results. To remove the LCD display, first open the lower portion of the analyzer and disconnect the ribbon cables J13 and J5 on the main board. The storage compartment and gas manifold module must also be removed. Next remove the four (4) screws which hold the LCD display assembly in place. The assembly can now be removed.

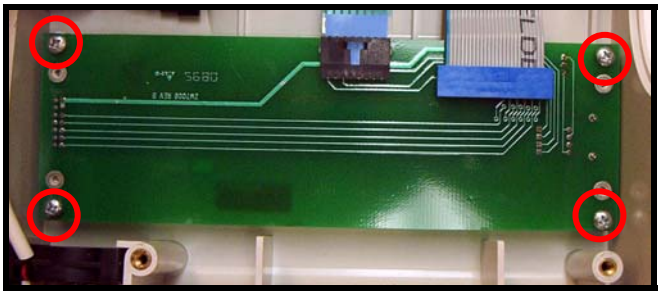


Figure 20: LCD back panel, fastening screws are circled

Installation

To reinstall the assembly, follow the removal instructions in reverse order. Before tightening the mounting screws, make sure to center the display over the window.

Verification

To test the display go to **DIAG3 - Disp** and press **ENTER**. Check if all dots are dark. If dots remain blank, the display assembly must be replaced.

Keypad

Removal

The keypad on the Osmetech OPTI CCA can be removed by first opening the lower portion of the analyzer. The flex cable from the keypad will now need to be disconnected from the display board. Use a knife to lift off the keypad from the analyzer housing.

Installation

Before replacement with a new keypad, the surface must be cleaned. Use alcohol to remove any adhesive which may be on the surface. The surface must be clean and dry before installing a new keypad. Take the new replacement keypad and remove the backing to expose the adhesive side of the keypad. Connect the keypad cable to the display board. Feed the cable through the grey slot in the analyzer housing. Carefully apply the new keypad to ensure proper alignment on the analyzer housing.

Caution: The keypad is attached to the housing of the analyzer with an adhesive backing and can not be re-used once removed from the analyzer.

Verification

To test the keypad go to **DIAG3 – Keypad** and press **ENTER**. Check if all the buttons result in the correct response. The keypad must be replaced in case of any malfunction or sluggish response.

Exhaust Fan

Removal

The Osmetech OPTI CCA is equipped with an internal exhaust fan which is used for cooling the electronic circuitry.

The fan is controlled by the software. T3 measures the air temperature inside the OPTI housing and is displayed in the **DIAG1 - Temp** menu. If T3 rises above 31.5 ° C, the fan is activated. If T3 drops below 30.5 ° C, the fan turns off.

To remove the fan, first open the lower portion of the analyzer. Disconnect connector J8 which attaches to the main board. One (1) screw fastens to the fan retainer and must be removed. Next remove the retainer and slide the fan out of the analyzer.

Installation

Install the new fan in reverse order.

Verification

To test the fan, go to **DIAG2 – Fan** and press **ENTER**. Verify proper fan operation by holding your hand over the rear vent covers. The fan will pull air through the air vents located on the bottom cover across the main board circuitry and through the cooling fan vent. An outward air flow should be felt at the cooling van vent. In case no air flow is felt, look through the vent cover to check if the fan blades turn. If the fan does not turn in full rotations or is noisy, then the fan must be replaced. A properly working fan should operate quietly and quickly cool the internal OPTI circuitry.

Storage Compartment

Located on the rear panel of the Osmetech OPTI CCA is a storage compartment. To disassemble the storage compartment, first separate the lower portion of the analyzer. Then, slide the storage compartment out of the upper housing. To replace the storage compartment, fit the grooved edges of the compartment over the upper housing and slide it into place. Each Osmetech OPTI CCA should have one Level 1 SRC, one Level 3 SRC and one Hb calibrator cassette.

Peristaltic Pump Motor

Removal

The peristaltic pump assembly is comprised of the pump motor and the peristaltic pump cartridge. During operation the peristaltic pump provides the necessary pump flow to move reagents, calibration gas and samples.
The peristaltic pump uses a stepper motor which is controlled by the main board and turns the pump roller in the pump cartridge to generate a small vacuum.
To remove the pump motor:

- Open the lower portion of the analyzer housing for access to the pump motor assembly and disconnect the pump motor cable **J7** from the main board.
- Open the printer cover and remove the pump cartridge.
- Open the printer cover and remove the four (4) pump motor mounting screws, accessed from the top (see Figure below).
- Remove the peristaltic pump motor by sliding the assembly out from the lower portion of the analyzer housing.

Figure 21: Peristaltic pump mounting screws (circled)

Installation

For reinstallation, reverse above steps.

Verification

To test the pump motor go to **DIAG3 – Pump** and press **ENTER**. The pump should turn counterclockwise for a brief moment, and then it should switch clockwise and rotate smoothly, without excessive noise through all speeds. If any of these conditions are not met the pump motor must be replaced.

Important Note

In case the pump hesitates on the fast speed, replace the pump cartridge and repeat the test.

Battery Receptacle

Removal

The Osmetech OPTI can be operated by either battery or by AC power.
To remove the battery receptacle, first remove the battery from the analyzer. The lower housing portion of the analyzer must be opened for access. Locate the battery receptacle and disconnect the internal cable **J3** from the main board. Next remove the two (2) retaining screws and pull the receptacle out of the analyzer.

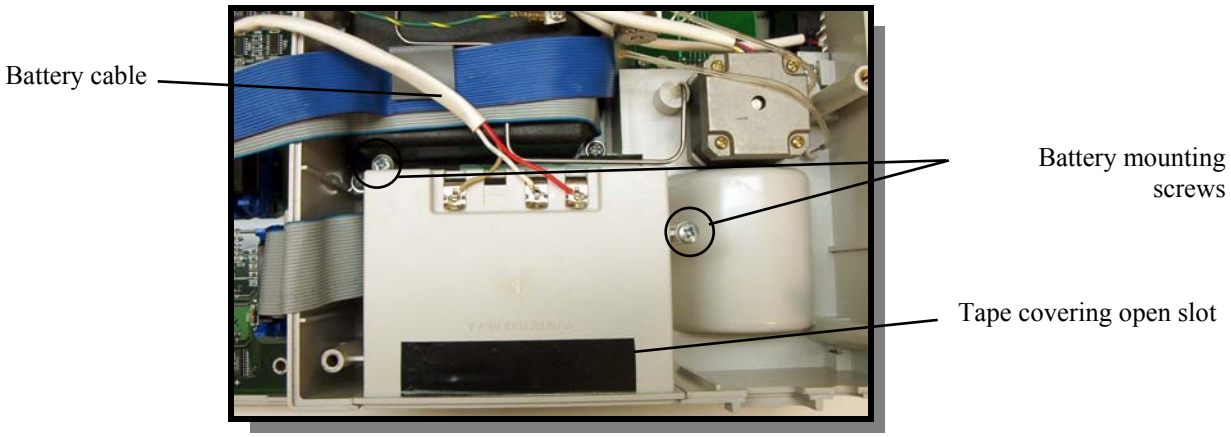


Figure 22: Battery receptacle screws (circled)

Installation

Follow the reverse order to install the new battery receptacle. Make sure the tape covering the bottom slots is in place (See Figure above).

Verification

To test the battery receptacle remove the battery. Turn the instrument on powered by the power supply. Check the battery charge LED on the backside of the instrument. The LED should be off. As the battery is inserted the LED should start blinking fast (4 times per second) or come-on solid. If this test passes, disconnect the power cord and verify that the instrument continues to operate.

Important Note

This part of the test requires a charged battery.

Figure 23: Location of the battery charge LED (circled)

Main Board Assembly

Important Note

The main board can only be replaced by a trained service technician.

Important Note

BT1 is a rechargeable lithium battery. In case this battery needs replacement, make sure to replace with the same type, Panasonic VL3032.

Barcode Reader

Removal

The internal barcode reader assembly is used to read the barcode data supplied with each cassette and Standard Reference Cassette (SRC). To access the internal barcode reader, first separate the upper and lower analyzer housing sections. Locate the barcode reader guide. Push on the latch and slide the guide downward. The module is held in place by retaining screws which must be removed. Disconnect cable **J14** from the main board. Pry out the window of the barcode reader with a screw driver and remove the assembly.

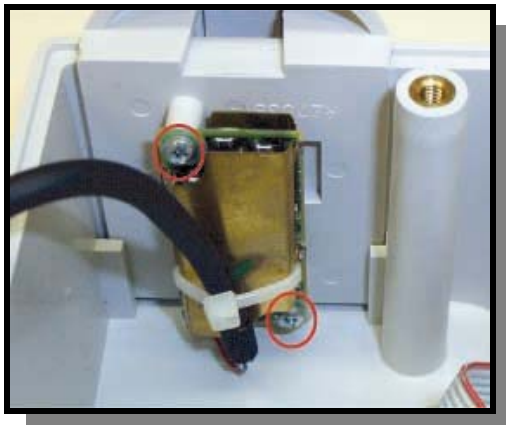


Figure 24: Barcode reader and screws (circled)

Barcode reader guide on opposite side of barcode reader module

Installation

Install the barcode reader module in reverse order. Make sure the replacement barcode reader has the copper foil around the black barrel as well as a cable tie to serve as a strain relief. Otherwise transfer these items form the old barcode reader before installation.

Verification

Go to **DIAG1 – Bcode** and swipe a cassette barcode. The cassette barcode should appear on the display screen.
Note: the displayed barcode is preceded with one additional character (signifies barcode type).

Osmetech OPTI CCA Systems S/N >4000

The Osmetech OPTI CCA is completely housed in a molded plastic case which provides a chassis for the electronic and mechanical assemblies. The analyzer is designed for quick removal of all major assemblies. Some of the components such as the printer, pump cartridge and top plate are accessible from the outside of the analyzer. The analyzer interior is accessible, after removing the bottom of the analyzer. The following chapter describes the removal of the major assemblies of the Osmetech OPTI CCA S/N >4000.

The Osmetech OPTI CCA S/N >4000 incorporates a new printer, redesigned main board and gas module. **It is not possible to upgrade Osmetech OPTI CCAs S/N <4000**. The main board, gas module and printer module are not backwards compatible to Osmetech OPTI CCAs S/N <4000.

Caution: Before disconnecting any analyzer assemblies disconnect the analyzer from primary power and remove the installed battery to avoid electrical damage

Pump Cartridge

Removal

The pump cartridge can be removed easily. Open the printer compartment cover to access the pump cartridge. Grasp the pump cartridge and pull straight up to free it from the pump motor shaft. The sticker on the pump cartridge contains the date of manufacture (DOM: WW – 2 digit calendar week; YY – 2 digit year).

The pump cartridge should be replaced if it is more than 12 months old.

Installation

To install the pump cartridge, first check whether the flat in the pump spool is aligned with the flat on the pump motor shaft. If the flat on the pump spool is not aligned, a coin can be used to turn the spool within the pump cartridge housing and align the pump spool with the motor shaft. The motor shaft may also be turned for easier reinstallation of the pump cartridge. For easiest alignment of the motor shaft, turn the motor shaft so the flat on the motor shaft is parallel to the right side of the analyzer housing with motor shaft flat to the right. Insert the pump cartridge and press down with a slight force so the cartridge fits onto the motor shaft and ensure the cartridge is seated into the pump ports. Press down on the pump spool to prevent the pump roller from binding on the pump cartridge housing, otherwise the pump will be noisy.

Verification

To break in the new pump, go to menu **DIAG1 – Gas** and continue to press **ENTER** to start a gas purge. Then go to **DIAG3 - Flow** to test the new pump cartridge. This test requires a cassette. It is allowable to use expired cassettes for this test. Before inserting the cassette, make sure the buffer in the cassette does not contain bubbles.

Press **ENTER** to start the test. In case the pump test fails, repeat the test.

In case of 3 subsequent failures, replace the pump cartridge.

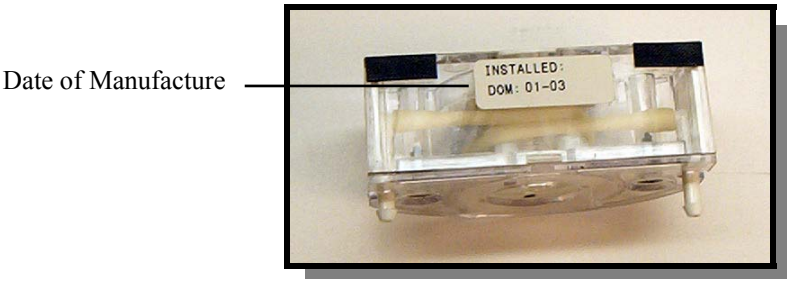


Figure 25: Peristaltic pump cartridge

Printer Assembly

Removal

To remove the printer assembly, first open the printer cover to gain access to the printer assembly. Remove the pump cartridge to allow enough free space for removing the printer assembly without interference in the printer compartment. The pump cartridge can be removed by grasping it and pulling it up. Next remove the printer paper and set aside. Two thumb screws which hold the printer assembly in place can now be loosened. After the thumb screws have been loosened, the printer can be slid towards the rear of the analyzer. Disconnect the printer ribbon cable that attaches to the printer. The printer assembly can now be removed.

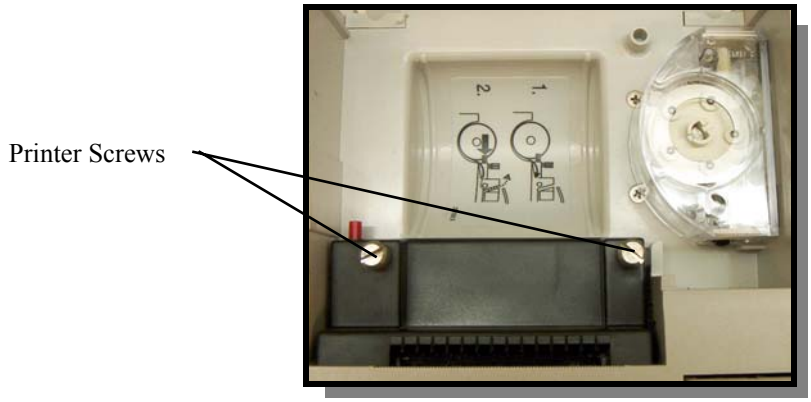


Figure 26: Printer assembly screws

Installation

The printer is installed in reverse sequence to removal. In case the printer mechanism is replaced, install the printer in reverse order of removal. Make sure the flex cable retainer is pulled up all the way before is plugging in the cables. Insert the cables in all the way, then push down the white cable retainers.

Printer trouble shooting

If the printer is...	Then…
Missing dots or not printing properly	the printer mechanism needs to be replaced. Cleaning the print head will not resolve the situation.
Paper feed is not advancing paper.	• Remove the printer and make sure the gray lever is pushed down all the way (see figure below) • Clean off all dust and dirt accumulation • Also note that the printer incorporates a paper sensor which will automatically disable the printer (including paper feed) in case paper is not inserted. • If problem continues remove printer shroud, lift grey lever to rear of printer assembly (open position) and clean any remaining debris. • If printer problems persist, replace printer.

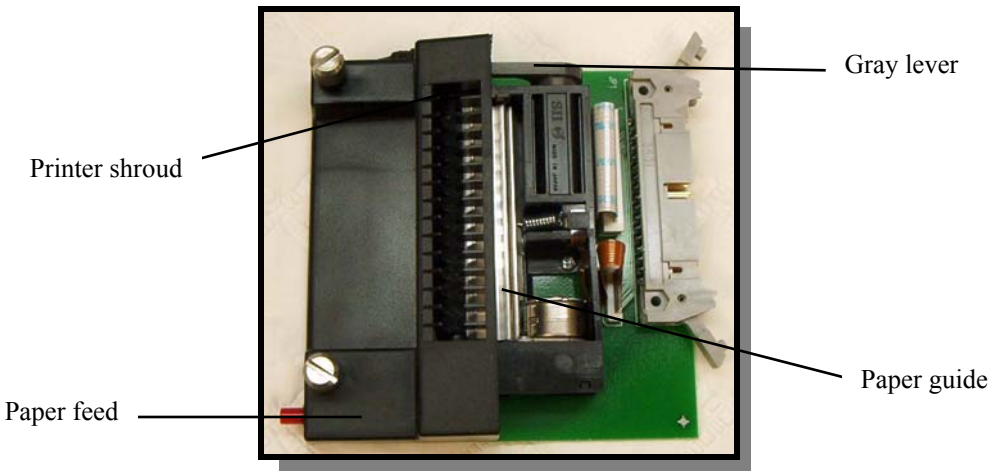


Figure 27: Printer mechanism

Verification

Go to menu **DIAG2- Printr** and perform a test print.

Remove and re-insert the paper. Make sure the printer auto-feeds the paper upon insertion.

Analyzer Housing

The main analyzer housing is comprised of two parts, the lower and upper housing. The assemblies located inside the analyzer can be removed. To gain access to these assemblies, the analyzer housings must be separated. To open the analyzer housing, first remove the battery on the left side of the analyzer. Turn the analyzer over to access the seven (7) screws securing the two housing sections together. Remove the screws and separate the upper and lower housing sections by flipping the lower housing open on the side of the carrying handle.

Caution: When turning the analyzer over to access the lower housing section, place the analyzer on a padded surface to prevent scratches or other damage to the upper housing section.

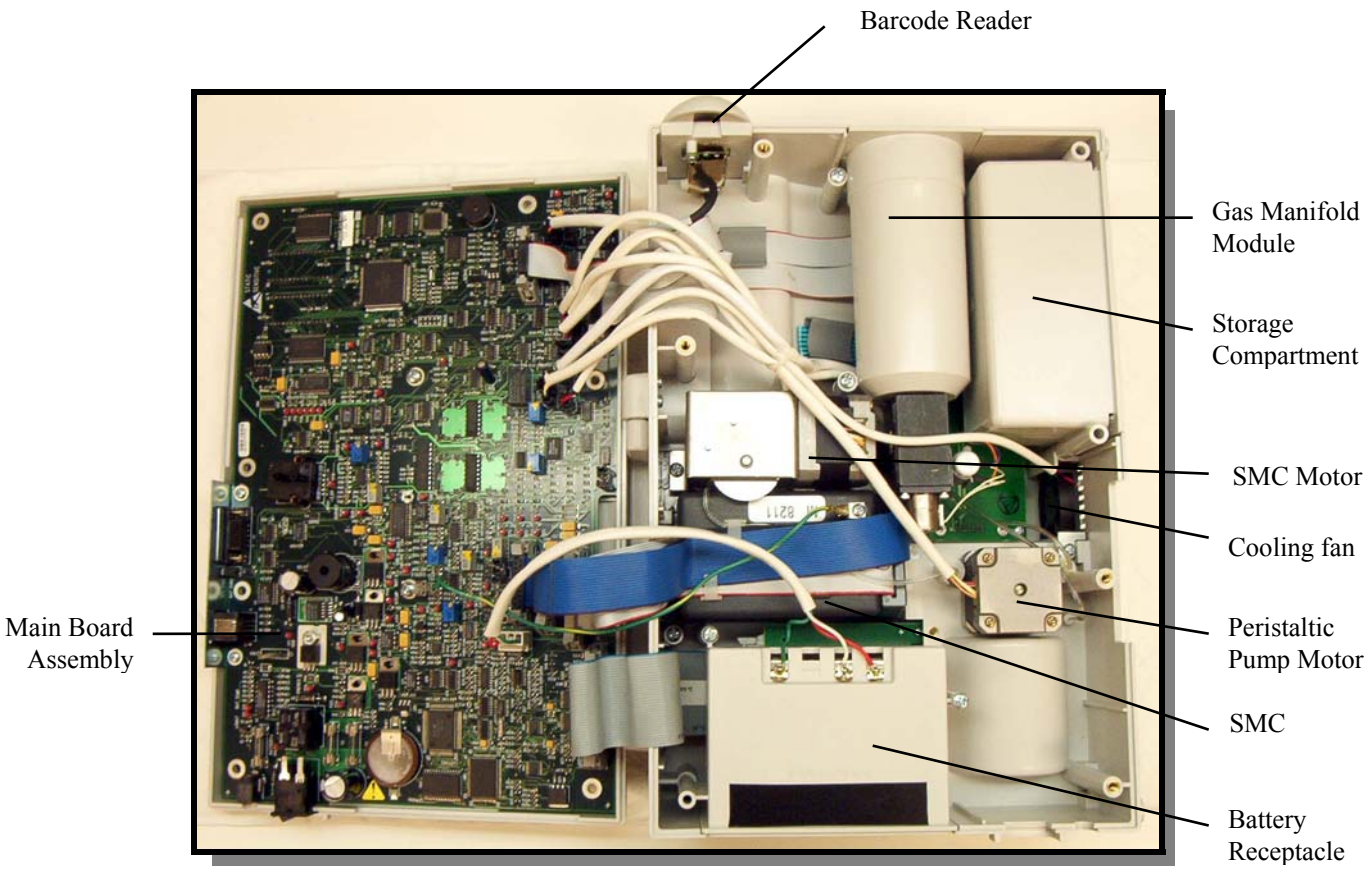


Figure 28: Opened OPTI CCA Analyzer

Sample Measurement Chamber Cover

Important Note

The SMC cover cannot be replaced due to the necessary tHb and SO2 calibration, which can only be performed by the manufacturer.

SMC Lower Module

Important Note

The SMC module can only be replaced by a trained service technician.

Osmetech OPTI CCA Handle

The Osmetech OPTI CCA is equipped with a carrying handle for easy transport. To remove the handle, first separate the lower portion of the analyzer. To access the handle, remove the battery compartment, gas manifold module and storage compartment (See the respective sections for removal instructions).
Next remove the four (4) self-tapping screws which hold the handle in place.

Pump Nipples

In case the pump nipples are damaged they need to be replaced. Damage usually occurs during removal of the pump receptacles. To remove damaged nipples, remove the pump cartridge and the pump receptacles open up the instrument, disconnect the tubes from the nipples and cut the nipples off flush with the housing (See Operator's Manual for pump receptacle removal procedures). Pull the remainder of the nipple out through the topside of the housing. The new nipples are inserted from the back of the housing with the large end pushed through the housing. To seat the nipples, use a suitable tool (small pliers) press hard against the base of the nipple, until it clicks in place.

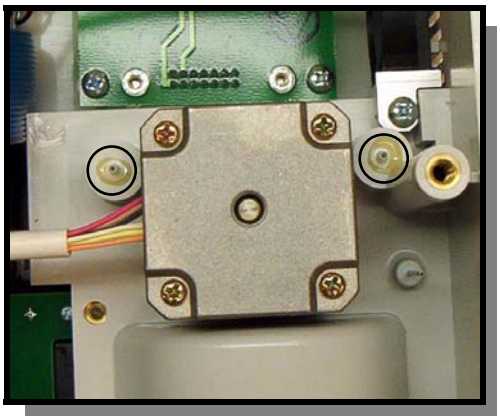


Figure 29: Peristaltic pump nipple connectors

Gas Manifold Module

Removal

The gas manifold module is located on the right rear side of the analyzer. The calibration gas cylinder is screwed into the module to form a gas-tight seal. The gas manifold module provides pressure regulation and controls the flow of gas when required for cassette calibration. To remove the module, first open the lower portion of the analyzer. Disconnect the Tygon tubes which connect to the peristaltic pump and clean-out port. Next disconnect the cable connectors J9 and JP6 on the Main Board. The module is held in place by two screws. After removal of these screws, the module may be pulled out of the analyzer.

To replace the Lee valve, desolder the wires from the old valve.

To remove the Aerodyne gas module, remove the two screws holding the gas manifold to the plastic housing.

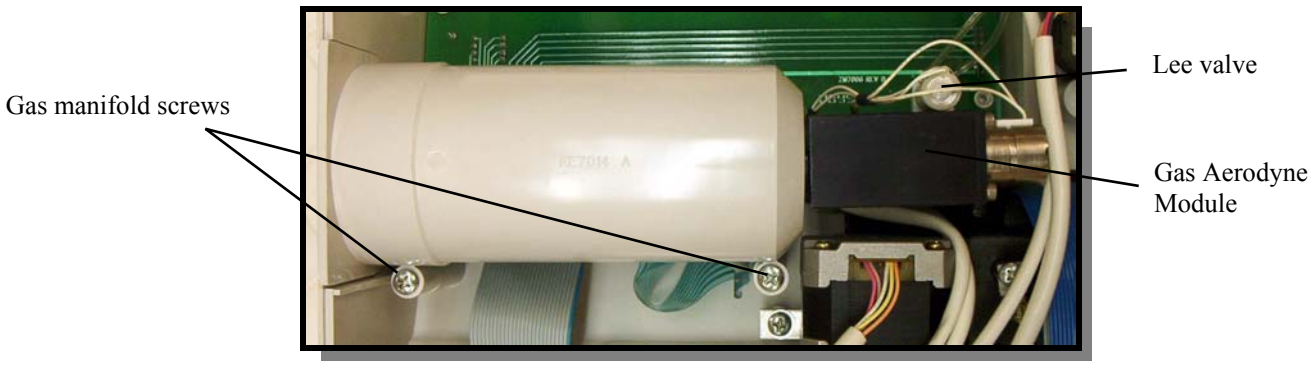


Figure 30: Gas manifold module

Installation

Upon reassembly, make sure the tubes from the clean-out port and the peristaltic pump are connected to the correct nipples. The tubes should *not* be crossed. To add a new Lee valve, resolder the wires of the new valve to the harness. The valve is not polarized. Add LockTite to the mounting screws. Do not over tighten the screws, since this may damage the valve.

To re-install the Aerodyne module, you must use **new** screws DS7000. The screws must be tightened such, that the two black rubber pads are compressed to a thickness of 1.6mm. Use a feeler gauge to check the compression.

Verification

To test an instrument for **gas leaks** proceed as follows:

- Make sure software revision AOPX2.24 or higher is installed.
- Install a gas bottle and go to **Diag1 – Gas** menu. The pressure gas remaining must be at least 50%. Make sure the printer has paper installed.
- Go to **Diag2 – FSET** and press **ENTER**. Type **"3350" ENTER** (password). Next select the menu item **GAS**. This will activate an automatic gas leak test, which will last 2 hours. After one hour, the unit will print a 1st pressure reading. At the end of the 2nd hour, the pressure is printed again.
- For the test to pass, the difference between the two pressures must be less than +/- 30 units.

In case of a leak (test failed) replace all tubing, the pump cartridge and the pump ports. Verify that the white nipples below the pump ports are intact (check both sides!). If available, replace the Lee gas valve. Repeat the test above, using a different gas bottle. In case of a repeat failure, the entire gas module needs to be replaced.

To test the **Aerodyne module output flow**, proceed as follows:

- Take a **full** gas bottle and insert the bottle into the OPTI.
- Go to **DIAG3 – Valve** and press **ENTER**. Press the right arrow key to de-activate the gas valves.
- Remove the pump cartridge.
- Press the left arrow key once and listen for gas coming out the rear pump port. Press the left arrow key right away to deactivate the gas valve.
- If you cannot hear the gas flow, the gas manifold module needs to be replaced.

Display Assembly

Removal

The Osmetech OPTI CCA uses a backlit LCD display module to display operating instructions and analyzer results. To remove the LCD display, first open the lower portion of the analyzer and disconnect the ribbon cable J13 and J5 on the main board. The storage compartment and gas manifold module must also be removed. Next remove the four (4) screws which hold the LCD display assembly in place. The assembly can now be removed.

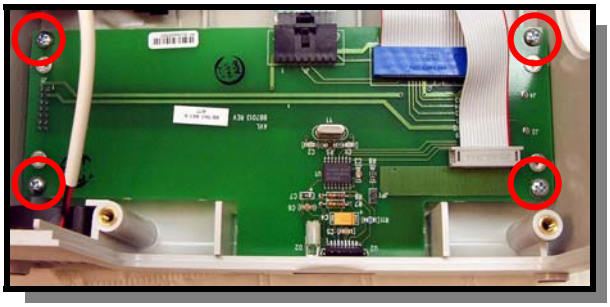


Figure 31: LCD back panel, fastening screws (circled)

Installation

To reinstall the assembly, follow the removal instructions in reverse order. Before tightening the mounting screws, make sure to center the display over the window.

Verification

To test the display go to **DIAG3 – Disp** and press **ENTER**. Check if all dots are dark. If dots remain blank, the display assembly must be replaced.

Keypad

Removal

The keypad fitted on the Osmetech OPTI CCA can be removed by first opening the lower portion of the analyzer. The flex cable from the keypad will now need to be disconnected from the display board. Use a knife to lift off the keypad from the analyzer housing.

Installation

Before replacement with a new keypad, the surface must be cleaned.
Use alcohol to remove any adhesive which may be on the surface. The surface must be clean and dry before installing a new keypad. Take the new replacement keypad and remove the backing to expose the adhesive side of the keypad. Connect the keypad cable to the display board. Feed the cable through the grey slot in the analyzer housing. Carefully apply the new keypad to ensure proper alignment on the analyzer housing.

Caution: The keypad is attached to the housing of the analyzer with an adhesive backing and can not be re-used once removed from the analyzer.

Verification

To test the keypad go to **DIAG3 – Keypad** and press **ENTER**. Check if all the buttons result in the correct response. The keypad must be replaced in case of any malfunction or sluggish response.

Exhaust Fan

Removal

The Osmetech OPTI CCA is equipped with an internal exhaust fan which is used for cooling the electronic circuitry.

The fan is controlled by the software. T3 measures the air temperature inside the OPTI housing and is displayed in the **DIAG1 - Temp** menu. If T3 rises above 31.5 ° C, the fan is activated. If T3 drops below 30.5 ° C, the fan turns off.

To remove the fan, first open the lower portion of the analyzer. Disconnect connector J8 which attaches to the main board. One (1) screw fastens to the fan retainer and must be removed. Next remove the retainer and slide the fan out of the analyzer.

Installation

Install the new fan in reverse order.

Verification

To test the fan go to **DIAG3– Fan** and press **ENTER**. Verify the proper fan operation by holding your hand over the rear vent covers. The fan will pull air through the air vents located on the bottom cover across the main board circuitry and through the cooling fan vent. An outward air flow should be felt at the cooling van vent. In case no air flow is felt, look through the vent cover to check if the fan blades turn. If the fan does not turn in full rotations or is noisy, then the fan must be replaced. A properly working fan should operate quietly and quickly cool the internal OPTI circuitry.

Storage Compartment

Located on the rear panel of the Osmetech OPTI CCA is a storage compartment. To disassemble the storage compartment, first separate the lower portion of the analyzer. Then, slide the storage compartment out of the upper housing. To replace the storage compartment, fit the grooved edges of the compartment over the upper housing and slide it into place. Each Osmetech OPTI CCA should have one Level 1 SRC, one Level 3 SRC and one Hb calibrator cassette.

Peristaltic Pump Motor

Removal

The peristaltic pump assembly is comprised of the pump motor and the peristaltic pump cartridge. During operation the peristaltic pump provides the necessary pump flow to move reagents, calibration gas and samples.
The peristaltic pump uses a stepper motor which is controlled by the main board and turns the pump roller in the pump cartridge to generate a small vacuum.
To remove the pump motor:

- Open the lower portion of the analyzer housing for access to the pump motor assembly and disconnect the pump motor cable **J7** from the main board.
- Open the printer cover and remove the pump cartridge.
- Open the printer cover and remove the four (4) pump motor mounting screws, accessed from the top (see Figure below).
- Remove the peristaltic pump motor by sliding the assembly out from the lower portion of the analyzer housing.

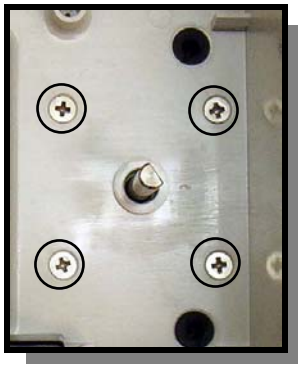


Figure 32: Peristaltic Pump mounting screws (circled)

Installation

For reinstallation, reverse above steps.

Verification

To test the pump motor go to **DIAG3 – Pump** and press **ENTER**. The pump should turn counterclockwise for a brief moment, and then it should switch clockwise and rotate smoothly, without excessive noise through all speeds. If any of these conditions are not met the pump motor must be replaced.

Important Note

In case the pump hesitates on the fast speed, replace the pump cartridge and repeat the test.

Battery Receptacle

Removal

The Osmetech OPTI can be operated by either battery or by AC power.
To remove the battery receptacle, first remove the battery from the analyzer. The lower housing portion of the analyzer must be opened for access. Locate the battery receptacle and disconnect the internal cable **J3** from the main board. Next remove the two (2) retaining screws and pull the receptacle out of the analyzer.

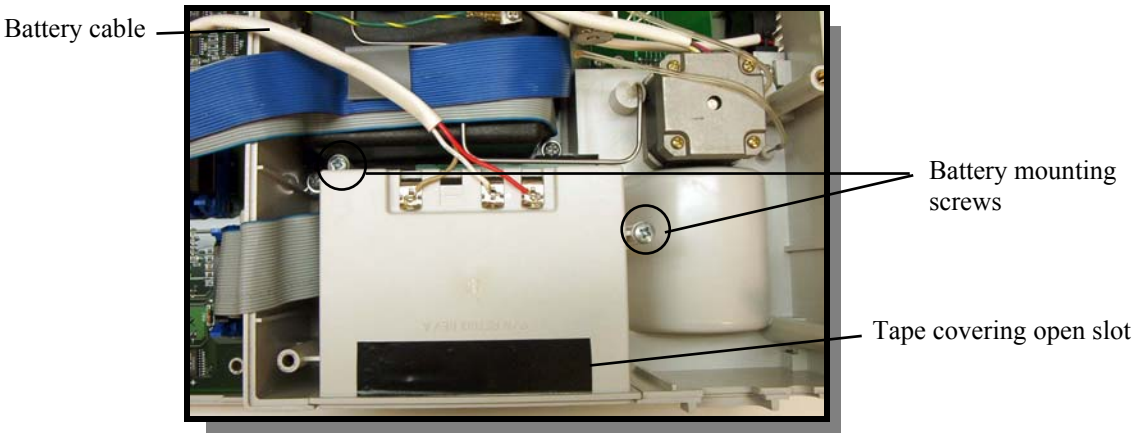


Figure 33: Battery Receptacle screws

Installation

Follow the reverse order to install the new battery receptacle. Make sure the tape covering the bottom slots is in place (See Figure above).

Verification

To test the battery receptacle remove the battery. Turn the instrument on powered by the power supply. Check the battery charge LED on the backside of the instrument. The LED should be off. As the battery is inserted the LED should start blinking fast (4 times per second) or come-on solid. If this test passes, disconnect the power cord and verify that the instrument continues to operate.

Important Note

This part of the test requires a charged battery.

Figure 34: Location of battery charge LED (circled)

Main Board Assembly

Important Note

The main board can only be replaced by a trained service technician.

Important Note

BT1 is a rechargeable lithium battery. In case this battery needs replacement, make sure to replace with the same type, Panasonic VL3032.

Barcode Reader

Removal

The internal barcode reader assembly is used to read the barcode data supplied with each cassette and Standard Reference Cassette (SRC). To access the internal barcode reader, first separate the upper and lower analyzer housing sections. Locate the barcode reader guide. Push on the latch and slide the guide downward. The module is held in place by retaining screws which must be removed. Disconnect cable **J14** from the main board. Pry out the window of the barcode reader with a screw driver and remove the assembly.

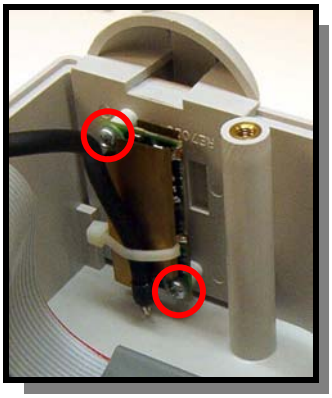


Figure 35: Barcode reader and screws (circled)

Installation

Install the barcode reader module in reverse order. Make sure the replacement barcode reader has the copper foil around the black barrel as well as a cable tie to serve as a strain relief. Otherwise transfer these items form the old barcode reader before installation.

Verification

Go to **DIAG1 – Bcode** and swipe a cassette barcode. The cassette barcode should appear on the display screen.
Note: the displayed barcode is preceded with one additional character (signifies barcode type).

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8 Service Spare Parts

Osmetech OPTI™ System

The Osmetech OPTI™ 1 and Osmetech OPTI™ CCA instruments are field repairable. Several assemblies require factory adjustment or alignment and field repair of these assemblies should be limited to assembly replacement. A list of recommended spare parts is provided below.

Recommended Spare Parts List

BB7013	PCB, DISPLAY, IR, OPTI CCA
BK7001	CABLE, PRINTER, OPTI 1
BK7004	CABLE, GROUNDING, OPTI 1/OPTI CCA
BP7010	ASSEMBLY, READER, BAR CODE, INTERNAL, OPTI 1/OPTI CCA
BP7013	ASSEMBLY, FAN, EXHAUST, OPTI 1/OPTI CCA
BP7015	ASSEMBLY, GAS MODULE, OPTI 1/OPTI CCA S/N<4000
BP7016	ASSEMBLY, DISPLAY, OPTI 1
BP7017	ASSEMBLY, RECEPTACLE, BATTERY OPTI 1/OPTI CCA
BP7022	ASSEMBLY, COVER, SMC, OPTI 1
BP7027	ASSEMBLY, MOTOR, PERI PUMP OPTI 1/OPTI CCA
BP7030	ASSEMBLY, HANDLE OPTI 1/OPTI CCA
BP7028	KIT, SFWR UPDATE, V1.14, US ENGLISH, OPTI 1
BP7039	KIT, SFWR UPDATE, V1.14, GERMAN, OPTI 1
BP7040	KIT, SFWR UPDATE, V1.14, FRENCH, OPTI 1
BP7041	KIT, SFWR UPDATE, V1.14, INTL ENGLISH, OPTI 1
BP7061	KIT, SFWR UPDATE, V1.14, SPANISH, OPTI 1
BP7060	SET, EPROM, PGMMED, OPTI 1/OPTI CCA
DF7001	SPRING, TORSION, SMC OPTI 1/OPTI CCA
DS7000	SCREW, PFH, 6-32 X .375, SELF OPTI 1/OPTI CCA
DS7001	SCREW, SPH, M2 X 14 OPTI 1/OPTI CCA
DS7003	SCREW, M4 X 25 OPTI 1/OPTI CCA
DS7004	SCREW, M4 X 50 PPH OPTI 1/OPTI CCA
DS7005	SCREW, THMB, SLOTTED, M 3.5 OPTI 1/OPTI CCA
DS7006	SCREW, M3 X 8, PFH OPTI 1/OPTI CCA
DS7007	SCREW, M4 X 12, OPTI 1/OPTI CCA

DS7008	SCREW, M4 X 76, OPTI 1/OPTI CCA
DS7009	SCREW, PPH, M2 X 6, OPTI 1/OPTI CCA
DS7012	SCREW, PPH, M3 X 6, OPTI 1/OPTI CCA
DS7014	SCREW, SS STEEL, PFH, M2 X 12 OPTI 1/OPTI CCA
DS7016	SCREW, PAN HEAD, PHILLIPS, M3 OPTI 1/OPTI CCA
DZ7004	WASHER, FLAT, NUMBER 8, OPTI 1/OPTI CCA
DZ7005	CAP, BLACK HEATER COVER, OPTI 1/OPTI CCA
EV7000	FUSE, 3.0A/250V SLOW-BLOW, OPTI 1/OPTI CCA
MB7000	PRINTER, THERMAL W/O BOARD, OPTI 1/OPTI CCA S/N <4000
MB7002	VALVE, GAS, 3 WAY, OPTI 1/OPTI CCA
MB7005	FOOT, ADHESIVE, OPTI 1/OPTI CCA
MB7014	PRINTER, THERMAL W/O BOARD, OPTI CCA S/N >4000
RE7009	PLATE, HINGE, OPTI 1/OPTI CCA
RE7010	HOUSING, MAIN, LOWER, OPTI 1/OPTI CCA
RE7014	HOUSING, GAS MODULE, OPTI 1/OPTI CCA
RE7018	GUIDE, BAR CODE, OPTI 1/OPTI CCA
RE7023	COMPARTMENT, STORAGE, OPTI 1/OPTI CCA
RE7024	DOOR, COMPARTMENT, STORAGE, OPTI 1/OPTI CCA
RE7025	LATCH, SMC COVER, OPTI 1/OPTI CCA
RE7027	LENS, BAR CODE, OPTI 1/OPTI CCA
RE7028	COVER, PRINTER ACCESS, OPTI 1/OPTI CCA
RE7029	COVER, EPROM, OPTI 1/OPTI CCA
RE7031	COVER, PRINTER, INNER, OPTI 1/OPTI CCA S/N<4000
RE7057	COVER, PRINTER, OPTI CCA S/N>4000
RE7032	PIVOT, HANDLE, OPTI 1/OPTI CCA
RE7034	RETAINER, COVER, PRINTER, OPTI 1/OPTI CCA
RE7036	FRAME, BAR CODE, OPTI 1/OPTI CCA
YB7001	PANEL, CONTROL, OPTI 1/OPTI CCA
YB7008	BRACKET, RETAINER, FAN, OPTI 1/OPTI CCA
YB7015	SPACER, GAS MODULE, OPTI 1/OPTI CCA
YB7018	GASKET, LOWER HSG, OPTI 1/OPTI CCA
YB7058	WINDOW, IR PORT, OPTI 1/OPTI CCA
ZB7002	LABEL, NAME PLATE, OPTI 1
ZB7005	LABEL, PAPER PATH, OPTI 1/OPTI CCA
ZB7026	LABEL, NAMEPLATE, OPTI CCA